

Highly Confidential - Subject to Further Confidentiality Review

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IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

- - -

IN RE: NATIONAL : HON. DAN A.  
PRESCRIPTION OPIATE : POLSTER  
LITIGATION :  
:  
APPLIES TO ALL CASES : NO.  
: 1:17-MD-2804  
:

- HIGHLY CONFIDENTIAL -

SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

VOLUME II

- - -

December 6, 2018

- - -

Continued videotaped deposition of  
GARY J. VORSANGER, Ph.D., M.D., taken  
pursuant to notice, was held at the law  
offices of Drinker Biddle & Reath, 105  
College Road East, Princeton, New Jersey,  
beginning at 9:20 a.m., on the above  
date, before Michelle L. Gray, a  
Registered Professional Reporter,  
Certified Shorthand Reporter, Certified  
Realtime Reporter, and Notary Public.

- - -

GOLKOW LITIGATION SERVICES  
877.370.3377 ph | 917.591.5672 fax  
deps@golkow.com

1 APPEARANCES:

2

3 SIMMONS HANLY CONROY, LLC  
4 BY: JAYNE CONROY, ESQ.  
5 112 Madison Avenue  
6 7th Floor  
7 New York, New York 10016  
8 (212) 784-6400  
9 jconroy@simmonsfirm.com

6

- and -

7

8 SIMMONS HANLY CONROY, LLC  
9 BY: SARAH BURNS, ESQ.  
10 One Court Street  
11 Alton, Illinois 62002  
12 (618) 259-2222  
13 Sburns@simmonsfirm.com  
14 Representing the Plaintiffs

11

12

13 O'MELVENY & MYERS, LLP  
14 BY: CHARLES LIFLAND, ESQ.  
15 400 South Hope Street, 18th Floor  
16 Los Angeles, California 90071  
17 (213) 430-6665  
18 clifland@omm.com

15

- and -

16

17 O'MELVENY & MYERS, LLP  
18 BY: VINCENT S. WEISBAND, ESQ.  
19 Times Square Tower  
20 7 Times Square  
21 New York, New York 10036  
22 (212) 326-2000  
23 vweisband@omm.com  
24 Representing the Defendants, Janssen  
and Johnson & Johnson

21

22

23

24

1 APPEARANCES: (Cont'd.)

2

3 PIETRAGALLO GORDON ALFANO BOSICK &  
4 RASPANTI, LLP

5 BY: ALEXANDER M. OWENS, ESQ.

6 1818 Market Street, Suite 3402

7 Philadelphia, Pennsylvania 19103

8 (215) 320-6200

9 amo@pietragallos.com

10 Representing the Defendant, Cardinal  
11 Health

12

13 TELEPHONIC APPEARANCES:

14

15 WEISMAN KENNEDY & BERRIS CO LPA

16 BY: DANIEL P. GOETZ, ESQ.

17 1600 Midland Building

18 101 W. Prospect Avenue

19 Cleveland, Ohio 44115

20 (216) 781-1111

21 dgoetz@weismanlaw.com

22 Representing the Plaintiffs

23

24 ALLEGAERT, BERGER & VOGEL, LLP

BY: MICHAEL S. VOGEL, ESQ.

BY: LOUIS A. CRACO, JR., ESQ.

111 Broadway, 20th Floor

New York, New York 10006

(212) 616-7060

mvogel@abv.com

lcraco@abv.com

Representing the Defendant,

Rochester Drug Corporation

20

COVINGTON & BURLING, LLP

21 BY: LAUREN C. DORRIS, ESQ.

22 850 10th Street, NW

Washington, DC 20001

(202) 662-6000

ldorris@cov.com

23 Representing the Defendant, McKesson  
24 Corporation

1 TELEPHONIC APPEARANCES: (Cont'd.)

2

JACKSON KELLY, PLLC  
3 BY: GRETCHEN M. CALLAS, ESQ.  
500 Lee Street East  
4 Suite 1600  
Charleston West Virginia 25301  
5 (304) 340-1169  
Gcallas@jacksonkelly.com  
6 Representing the Defendant,  
AmerisourceBergen

7

8 ARNOLD PORTER KAYE SCHOLER, LLP  
BY: RYAN Z. WATTS, ESQ.  
9 601 Massachusetts Avenue, NW  
Washington, DC 20001  
10 (202) 942-6609  
Ryan.watts@arnoldporter.com  
11 Representing the Defendants, Endo  
Health Solutions Endo  
12 Pharmaceuticals, Inc.; Par  
Pharmaceutical Companies, Inc. f/k/a  
13 Par Pharmaceutical Holdings, Inc.

14

FOX ROTHSCHILD, LLP  
15 BY: JACOB S. PERSKIE, ESQ.  
1301 Atlantic Avenue  
16 Midtown Building, Suite 400  
Atlantic City, New Jersey 08401  
17 (609) 348-4515  
Jperskie@foxrothschild.com  
18 Representing the Defendant, Validus  
Pharmaceuticals

19

20 WILLIAMS & CONNOLLY, LLP  
BY: JOSEPH S. BUSHUR, ESQ.  
21 725 12th Street, NW  
Washington, D.C. 20005  
22 (202) 434-5148  
Jbushur@wc.com  
23 Representing the Defendant, Cardinal  
Health

24

1 TELEPHONIC APPEARANCES: (Cont'd.)

2

3 HUGHES HUBBARD & REED, LLP  
4 BY: TINA M. SCHAEFER, ESQ.  
2345 Grand Boulevard  
5 Kansas City, Missouri 64108  
(816) 709-4159  
6 tina.schaefer@hugheshubbard.com  
Representing the Defendant, UCB,  
7 Inc.

8 JONES DAY  
9 BY: RICHARD M. BRODSKY, ESQ.  
150 West Jefferson Street  
10 Suite 2100  
Detroit, Michigan 48226-4438  
(313) 733-3939  
rbrodsky@jonesday.com  
11 Representing the Defendant, Walmart  
12

13 CLARK MICHIE, LLP  
14 BY: BRUCE CLARK, ESQ.  
103 Carnegie Center, Suite 300  
15 Princeton, New Jersey 08540  
(609) 423-2144  
bruce.clark@clarkmichie.com  
Representing the Defendant, Pernix

16  
17 ALSO PRESENT:

18  
19 VIDEOTAPE TECHNICIAN:

20 Dan Holmstock

21  
22  
23  
24

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1                                   -   -   -  
 2                                   I N D E X  
 3                                   -   -   -

4  
 5           Testimony of:

6                                   GARY J. VORSANGER, Ph.D., M.D.

7                   By Ms. Conroy           431, 603, 706

8                   By Mr. Lifland               470, 704

9  
 10  
 11                                   -   -   -  
 12                                   E X H I B I T S  
 13                                   -   -   -

14			
15	NO.	DESCRIPTION	PAGE
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21		Study of Health-Related	
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22		Pain Outcomes in Chronic	
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24		(Kosinski)	

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10	Janssen		
11	Vorsanger-15	Duragesic Fourth Risk Management Plan Progress Report	552
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14	Vorsanger-16	Cumulative Review Of Iatrogenic Addiction Associated with the Use Of Transdermal Duragesic Fentanyl Patch	559
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17	Janssen		
18	Vorsanger-17	What Percentage of Chronic Nonmalignant Pain Patients Exposed To Chronic Opioid Analgesic Therapy Develop Abuse/Addiction And/or Aberrant Drug Related Behaviors? A Structured Evidence Based Review (Fishbain)	562
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16		Duragesic, Fentanyl	
17		Transdermal System	
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19	Janssen		
20	Vorsanger-21	Evaluation of the	582
21		Tamper-Resistant	
22		Properties of	
23		Tapentadol	
24		Extended-Release Tablets	
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12		JAN-MS-00228548	
13	Janssen		
14	Vorsanger-23	E-mail Thread	661
15		2/6/13	
16		Subject, More Project	
17		Deliverables Needed	
18		& Attachment Totality	
19		Close Out	
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21	Janssen		
22	Vorsanger-24	E-mail Thread	696
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29		Subject, Draft Pain	
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9		HCC Promotional Speaker	
		Bureau Training	
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2 DEPOSITION SUPPORT INDEX

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4

5 Direction to Witness Not to Answer

6 PAGE LINE

None.

7

8 Request for Production of Documents

9 PAGE LINE

None.

10

11 Stipulations

12 PAGE LINE

None.

13

14 Questions Marked

15 PAGE LINE

None.

16

17

18

19

20

21

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23

24

1                   THE VIDEOGRAPHER: The time  
2                   is 9:20 a.m. December 6, 2018.  
3                   This is Video 1, Volume II of the  
4                   continued videotaped deposition of  
5                   Dr. Gary Vorsanger.

6                   A reminder to the witness.  
7                   You're still under oath. Counsel,  
8                   you may proceed.

9                                 - - -

10                  ... GARY J. VORSANGER, Ph.D. M.D.,  
11                  having been previously sworn, was  
12                  examined and testified as follows:

13                                 - - -

14                                 CONTINUED EXAMINATION

15                                 - - -

16                  BY MS. CONROY:

17                  Q.       Good morning, Doctor.

18                  A.       Good morning.

19                  Q.       Let me pass to you what I've  
20                  marked as Exhibit 12.

21                                 (Document marked for  
22                                 identification as Exhibit  
23                                 Janssen-Vorsanger-12.)

24                  BY MS. CONROY:

1           Q.     This Exhibit 12 was a native  
2     production. The number is  
3     JAN-MS-02321524.

4                     And it doesn't have a cover  
5     e-mail that I could find. It was in your  
6     custodial file, Doctor. And it's  
7     entitled -- appears to be a PowerPoint  
8     entitled "risk management plan for our  
9     products," May 9th of 2005.

10                    If you turn to Page 2 of the  
11     slide deck there's a graphic. It says,  
12     "What are our goals and intent? Risk  
13     management" -- "risk management  
14     strategy."

15                    Does this document look  
16     familiar to you, Doctor?

17           A.     Yes, it does.

18           Q.     Would you have prepared the  
19     slide deck?

20           A.     I would have provided the  
21     materials for the content of it. I may  
22     or may not have been the one that  
23     actually did the PowerPoint presentation.

24           Q.     I see in the lower left-hand

1 corner, it has RMP, and then across JOMPC

2 Do you know what that stands for?

3 A. The RMP would be the rim  
4 plan. And I don't recall what JOPC (sic)  
5 is.

6 Q. As we go through this, if --  
7 if it rings a bell what JOPC means --  
8 JOMPC, would you let me know?

9 A. Yeah.  
10 Oh, I didn't see the M. It  
11 was -- I think it's Janssen Ortho-McNeil  
12 Pharmaceutical.

13 Q. Great. Okay. And I think  
14 we saw on your CV yesterday at some  
15 point, that's the way, your title had  
16 Janssen Ortho-McNeil in it?

17 A. Yes, yes, that's correct.

18 Q. At this period of time were  
19 you -- was the company and yourself  
20 trying to determine whether to have a  
21 risk management plan?

22 A. So there were activities  
23 going on to monitor as an -- on an  
24 ongoing basis. They were --

1 pharmacovigilance programs and there were  
2 analysis that the company were  
3 undertaking. In 2005 I had already  
4 started to look at initiating other pilot  
5 programs, but we were interested in  
6 having it formalized a little bit to have  
7 a more specific risk management  
8 program -- a risk management plan by a  
9 risk management team that could begin to  
10 address that.

11 Q. Were there other risk  
12 management plans in place at the company,  
13 do you know?

14 A. We -- we had some pilot  
15 programs going on. And there were  
16 activities that were going on.

17 Q. Okay. And what -- the pilot  
18 programs, what drugs did they involve?

19 A. They were involved with the  
20 Duragesic transdermal fentanyl system.

21 Q. If you turn the page to  
22 Page 3, please, which is strategic  
23 imperatives. And the number one  
24 strategic imperative is to ensure patient

1 access to our meds. Do you see that?

2 A. Yes.

3 Q. And this would -- the way  
4 you would do that I guess, if I'm -- if I  
5 understand the way this slide works, is  
6 that to ensure patient access to meds,  
7 you would provide educational materials  
8 to healthcare professionals. Do you  
9 agree?

10 A. Yes.

11 Q. And that you would ensure  
12 supply chain integrity?

13 A. The resupply chain integrity  
14 would be ensured by the company.

15 Q. What does that mean?

16 A. That means that the people  
17 responsible at the company for supply  
18 chain integrity would be -- have  
19 processes in place to do that type of  
20 work.

21 Q. Would that be you or someone  
22 else?

23 A. It would be someone else.

24 Q. And what departments if you



1 know?

2 A. The -- at Janssen there's a  
3 supply chain group and there's a trade  
4 group, and they are responsible for the  
5 supply chain activities.

6 Q. Supply group and a trade  
7 group?

8 A. Yes.

9 Q. And would you be working  
10 with them to formulate this risk  
11 management strategy?

12 A. They would be -- they would  
13 have put together their plan and the  
14 processes that they have in place and  
15 that that information would be brought  
16 into and shared with this -- the other  
17 group of people. So it would be  
18 individuals like myself in the medical  
19 group and other people from regulatory.  
20 And the supply folks responsible for  
21 supply chain would bring their  
22 information to it as well.

23 Q. And then together you would  
24 work on the risk management plan?

1 A. Yes.

2 Q. Do you recall any of the  
3 individuals from either supply or trade  
4 that would have worked on the risk  
5 management plan?

6 A. Not at this time.

7 Q. Then the second imperative  
8 is to limit abuse and diversion of our  
9 products. That would be done through  
10 education. Would you agree?

11 A. Yes.

12 Q. Timely identification and  
13 follow-up.

14 Identification of what?

15 A. If there were any events  
16 that were related to abuse and diversion  
17 that we became aware of, that we would  
18 ensure that those were followed up and we  
19 had all of the information and what  
20 happened. And then through that, we  
21 would begin to see whether we could  
22 modify our educational process to address  
23 those issues as they came up.

24 Q. And who would be responsible

1 for that follow-up?

2 A. It would be depending on the  
3 nature of what had happened, whether it  
4 would be -- you know, if there was  
5 something that -- for example, diversion  
6 would be an illegal activity and that  
7 would be turned over to ensure that the  
8 right people followed up on that illegal  
9 activity.

10 Q. Would they be -- would  
11 follow-up be initially done by internal  
12 J&J individuals?

13 A. It certainly could have  
14 been. And then if the authorities needed  
15 to be brought in as well, then that would  
16 happen as well.

17 Q. So it was contemplated at  
18 this time that you may, in fact, have to  
19 go outside the company for follow-up?

20 A. For something like  
21 diversion, which as I mentioned is an  
22 illegal activity, it would be discussed  
23 and a determination would be made, yes.

24 Q. And what is your

1 understanding of diversion, what would --  
2 what would -- well, how would you define  
3 diversion?

4 A. Well, the product was  
5 diverted from the normal way in which it  
6 would be used by distributors,  
7 pharmacists, et cetera. That it was  
8 rather for illegal use.

9 Q. And who -- who in the group  
10 would identify if diversion took place?

11 A. It would have been  
12 individuals responsible for the supply  
13 chain integrity. They would just report  
14 that to the group. And then they would,  
15 as I mentioned earlier, have processes in  
16 how they would deal with it.

17 Q. So that would be supply and  
18 trade?

19 A. Yes.

20 Q. And your identification of  
21 just diversion, just so that I  
22 understand, it would be drugs that would  
23 be routed for illegal use from either a  
24 distributor or a pharmacy?

1           A.     That would be one way. If  
2 we became aware for example, if other  
3 places where diversion was occurring, we  
4 would follow up as needed.

5           Q.     And how would you hear about  
6 diversion?

7           A.     Well, the supply chain  
8 individuals would hear about it through  
9 their process as well. If we were aware  
10 that there was diversion going on in an  
11 area, then we might send investigators in  
12 to understand the nature of that  
13 diversion.

14          Q.     And would you learn about  
15 diversion -- or is one way that you would  
16 learn about diversion from some of the  
17 data that was being collected at Johnson  
18 & Johnson?

19          A.     Potentially some of the  
20 information as I already mentioned from  
21 them, and then if there was information  
22 that would be coming in later on through  
23 groups like RADARS. That would have been  
24 coming at a later date.

1           Q.     And I think we saw -- we saw  
2     yesterday a document that had some data  
3     from IMS that could identify hotspots and  
4     such. Would that be one of the ways that  
5     you -- or that maybe not you yourself,  
6     but supply or trade could identify areas  
7     of diversion?

8           A.     Whatever the --

9                   MR. LIFLAND: Object to the  
10     form of the question.

11                  THE WITNESS: That would be,  
12     again through the supply chain  
13     individuals making those types of  
14     determinations. It wouldn't be  
15     something that medical  
16     specifically would be addressing.

17   BY MS. CONROY:

18           Q.     Do -- did supply and trade  
19     have access to the IMS data?

20           A.     I don't know.

21           Q.     You did -- you had access to  
22     IMS data?

23           A.     Not directly.

24           Q.     Who did?

1           A.     There were other groups  
2     for -- the outcomes research for example,  
3     may have had that. Other groups within  
4     the company that may have used that.  
5     That may have been for different  
6     purposes, not as you are suggesting for  
7     diversion but for other types of  
8     analysis.

9           Q.     Did you have any -- did you  
10    yourself have any restrictions if you  
11    wanted to see particular data from IMS?

12          A.     No.

13          Q.     And that was true throughout  
14    the time at Johnson & Johnson?

15          A.     Yes. If there was a request  
16    for particular data, yes.

17          Q.     And then if you look at the  
18    Imperative Number 3, "Ensure the  
19    integrity of our products after  
20    manufacturing," and that's done with the  
21    bullet point, "Extend quality control of  
22    our products using newest" -- "newest  
23    technologies."

24                   What does that mean?

1           A.     Again, these were the other  
2 individuals involved in the manufacturing  
3 process. And whatever processes they had  
4 in place for quality control, which were  
5 accepted by the company.

6           Q.     And then partnering along  
7 the entire supply chain. Maybe that's  
8 part of the first bullet point. Do you  
9 know?

10          A.     I'm not sure.

11          Q.     Okay. But the -- but  
12 quality control would be extended  
13 throughout the entire supply chain. Is  
14 that fair to say?

15          A.     Yes.

16          Q.     If you go to Page 12. This  
17 slide says, "Unification of findings,  
18 pulling it all together." And then the  
19 first bullet point is "information from  
20 active surveillance and passive  
21 surveillance and supply chain  
22 distribution sources submitted to members  
23 of the internal advisory board."

24                   Now, you told me supply



1 chain distribution, that would be supply  
2 and trade, correct?

3 A. They would have those  
4 responsibilities.

5 Q. And active surveillance, who  
6 would have that responsibility?

7 A. So in order to answer your  
8 question we have to go back and look at  
9 the composition of that. So active  
10 surveillance would be done initially by  
11 the risk management team. That would --  
12 I'm trying to find the right slide to go  
13 through that with you.

14 Q. Okay.

15 A. And those would be -- I  
16 think it's -- it's not labeled -- RMP  
17 strategy, building the plan.

18 Q. I see it. Okay.

19 A. Yes. So first, risks would  
20 be identified again by management or the  
21 assessment. And as we'd be going through  
22 our clinical studies, our in vitro and  
23 nonclinical studies and clinical abuse  
24 liability. Some of the assessments that

1 we would be making.

2 And then the people who  
3 would initially be reviewing some of that  
4 would be from the risk management team.

5 And individuals who sat on the risk  
6 management team were people involved in  
7 product labeling from our regulatory  
8 group. They'd have other ways in which  
9 that would be done for education and  
10 promotional activities to make sure that  
11 we have that. There would be  
12 surveillance ongoing and there were two  
13 types of surveillance: Active and  
14 passive surveillance. And I can explain  
15 those.

16 Q. Yes. I would like you to.

17 A. And we talked about  
18 already -- about the supply chain --  
19 supply chain.

20 Q. Yes.

21 A. So passive surveillance  
22 would be nothing -- it's nothing really  
23 passive about passive surveillance. It's  
24 an entity and activities that would be

1 going on through our pharmacovigilance  
2 group. And passive refers to the fact  
3 that the information would be coming  
4 through the company either through  
5 MedWatch forms or through people calling  
6 in about adverse events.

7                   The active surveillance is  
8 an activity where we would go out and  
9 gain that information, and that would be  
10 through groups like RADARS and Inflexxion  
11 and getting that type of information.  
12 And those data would be reviewed by the  
13 risk management team.

14               Q.     And would the risk  
15 management team -- is that who would be  
16 responsible for surveillance or would  
17 there be a different group?

18               A.     Yeah, so the risk management  
19 team would be reviewing the data coming  
20 in from RADARS and from Inflexxion. They  
21 would also be discussing or be talking to  
22 the source from passive surveillance as  
23 well. And that information would be  
24 reviewed and discussed and shared with

1 the internal advisory board, which was  
2 senior level individuals at Janssen, and  
3 discuss the activities, what was  
4 happening, if there were any concerns so  
5 that senior leadership would be able to  
6 get involved quickly as needed.

7 Q. And does that mean when I  
8 look over here on the left-hand side  
9 where it says management, would that be  
10 the internal advisory team?

11 A. That's -- yes. Management  
12 would be the internal advisory team. And  
13 then the changes that the management  
14 might discuss and decide on would be  
15 changes to the product labeling if that  
16 was appropriate, modifications of our  
17 educational systems as needed to address  
18 this, ensure that our launch and  
19 promotional activities were correctly  
20 reflecting what we knew. And then  
21 continue up with our surveillance, I've  
22 already discussed. And distribution and  
23 supply chain we already discussed.

24 Q. You may have told me this

1 and I missed it. On the right-hand side,  
2 assessment of the risks. Who is doing  
3 the assessment of the risks, what team  
4 members?

5 A. I'm sorry. Oh, yes. So  
6 those would be the activities by the risk  
7 management team.

8 Q. Okay.

9 A. Yes.

10 Q. Would that also be the  
11 internal advisory team?

12 A. So the internal advisory  
13 team would receive the initial findings  
14 from the risk management team and  
15 certainly have an opportunity to review  
16 the information themselves to make their  
17 own determination.

18 Q. I see. Okay. So let's go  
19 back to Slide 12 where it says, "Putting  
20 it all together." And now I think it  
21 makes more sense. So information from  
22 active surveillance and passive  
23 surveillance and supply chain  
24 distribution would be submitted to

1 members of the internal advisory board.

2 And that was when it makes its way back  
3 up to management, correct?

4 A. Yes.

5 Q. Identical information is  
6 given to the external advisory board.  
7 Who is that?

8 A. So the external advisory  
9 board were a group of individuals outside  
10 the company, with knowledge and expertise  
11 in different areas that would help guide  
12 us on appropriate tactics to take if we  
13 became aware of addiction.

14 And there was -- so -- and I  
15 think we just -- so that's the -- if you  
16 want more information I can discuss that.

17 Q. Okay. How were they chosen?

18 A. They were chosen based on  
19 their background and expertise. So we  
20 wanted to have an individual who had  
21 expertise in FDA activities and  
22 appropriate product labeling. We wanted  
23 an individual with experience with DEA.  
24 We also wanted someone who had background

1 in pain management who is a pain expert.

2 Because active surveillance  
3 was a -- some new methodology, we wanted  
4 someone who had experience in signal  
5 detection methodology. So that would be  
6 an individual who could help us  
7 understand what's a signal and what's not  
8 a signal and then help us begin to think  
9 about that.

10 And the other person that we  
11 added on was bioethicist because we  
12 wanted to get an outside opinion on some  
13 of the activities we're doing and see --  
14 and kind of checking with them as well.

15 Q. And that would -- that would  
16 be the external advisory board, those --  
17 those individuals --

18 A. Yes.

19 Q. -- that had those skills?

20 And who would -- who would  
21 be choosing those individuals?

22 A. Those were individuals that  
23 I selected in discussion with other  
24 people in the company. But again based

1 on their background and expertise.

2 Q. Had anything like that been  
3 done at Johnson & Johnson prior to this?

4 A. Not to my knowledge.

5 Q. And then I see that each  
6 board, the internal board and the  
7 external board makes an independent  
8 assessment of the information to  
9 determine if there is an actionable  
10 signal.

11 A. Yes.

12 Q. Do you agree with that?

13 A. Yes.

14 Q. And then in the event they  
15 disagree, the more conservative  
16 recommendation is followed. I take it at  
17 some point each -- the internal and  
18 external boards learns of each other's  
19 decisionmaking process, and the more  
20 conservative approach is taken?

21 A. Yes.

22 Q. Was there anyone that would  
23 preside over both boards?

24 A. So I -- I presided over the



1 external review committee and was  
2 responsible also for the risk management  
3 team and we interacted with the internal  
4 review committee as we've described.

5 Q. Okay. Is this structure  
6 still in place?

7 A. I don't know at this point.

8 Q. Was it in place when you  
9 left the company?

10 A. The risk management team, to  
11 the best of my knowledge, had been  
12 superseded by a different team, but some  
13 of its elements that you have seen here  
14 were taken on by that team.

15 Q. And who headed up that team,  
16 the one that took over?

17 A. That was, I believe headed  
18 up by the pharmacovigilance group.

19 Q. And so did the pharmaco --  
20 did the pharmacovigilance team keep an  
21 external and an internal structure?

22 A. The external structure was  
23 continued for a while, but I don't know  
24 whether it was part of the team that was

1 run by the pharmacovigilance group.

2 Q. Do you recall approximately  
3 when it switched to the pharmacovigilance  
4 group?

5 A. I don't recall.

6 Q. And do you recall any of the  
7 individuals who were on the external  
8 board?

9 A. Yes.

10 Q. And who were they or who do  
11 you remember?

12 A. Right, so the person who was  
13 -- had acute -- very knowledgeable about  
14 FDA activities and product labeling, the  
15 person was Dr. Cynthia McCormick, former  
16 head of -- director of the anesthetics  
17 and critical care. I'm paraphrasing the  
18 title of the FDA group. The name of the  
19 group is probably a little -- may be a  
20 little bit different from that.

21 Q. Okay.

22 A. The person from DEA who  
23 participated on the external advisory  
24 board was Mr. Frank Sapienza. The pain

1 specialist who we had was Dr. James Otis  
2 up in Boston. The person that helped us  
3 with signal detection methodology, we  
4 talked about active surveillance and  
5 those things, I'm blocking on her name  
6 right now. And the last person was the  
7 bioethicist, and that was Dr. Art Kaplan.

8 Q. Dr. Art Kaplan?

9 A. Yes.

10 Q. With a K?

11 A. Yes.

12 Q. And it was a woman -- is she  
13 a physician for the signal detection, do  
14 you recall?

15 A. Yes. I'm blocking on her  
16 name though. Yes.

17 Q. If you can turn to Slide 23.

18 A. Oh I remember now.

19 Dr. Annette Stemhagen.

20 Q. Stemhagen?

21 A. Stemhagen. I believe --

22 Q. Stemhagen.

23 A. Yes, I believe that's her  
24 last name.

1           Q.     Okay.  Actually Slide 22  
2     might make it a little easier to talk  
3     about.  Education would be one of the  
4     ways that risk management would get  
5     information out to the field; is that  
6     correct?

7           A.     Yes.

8           Q.     And one would be approved  
9     information from the label going directly  
10    to the healthcare professionals through  
11    continuing medical education.  Do you see  
12    that?

13          A.     Yes.

14          Q.     And you agree that was one  
15    way?

16          A.     Yes.

17          Q.     And information obtained as  
18    the result of findings from the supply  
19    chain distribution could also be  
20    communicated through lectures on abuse  
21    and diversion.

22                   Do you see that?

23          A.     Yes.

24          Q.     Would those be CME lectures

1 or something else?

2 A. This is under the category  
3 of CME, so presumably it would be a  
4 discussion under CME.

5 Q. And it says launch  
6 promotional materials would have no  
7 impact on CME. What do you mean by that?

8 A. This was a separation of  
9 promotional activities from CME.

10 Q. So CME would not have the  
11 same restrictions?

12 A. CME would not have the same  
13 restrictions that we would have.  
14 Whatever the guidelines for CME are,  
15 those are the ones that the company would  
16 follow. But promotional materials would  
17 not be part of CME discussion.

18 Q. Okay. And then if you turn  
19 to Slide 23, this is the -- this is now  
20 separate. This is the promotional piece,  
21 correct?

22 A. Yes.

23 Q. And approved information as  
24 a result of labeling change would be

1 directly transmitted to healthcare  
2 professionals through promotional  
3 activities. That would be, for example,  
4 by sales representatives, correct?

5 A. Yes.

6 Q. And then information  
7 obtained through surveillance of supply  
8 chain distribution might be communicated  
9 in general discussions on abuse and  
10 diversion. How would -- that would be  
11 considered promotion, correct?

12 A. So the information would  
13 need to be disseminated according to the  
14 company processes for formal promotional  
15 material and how to make that -- so it  
16 was an awareness about those types of  
17 activities.

18 Q. And would those -- would  
19 this be general discussions on abuse and  
20 diversion through the supply chain?

21 A. The -- the way I read this  
22 would be the information obtained through  
23 the surveillance of supply chain  
24 distribution might be communicated in

1     general discussions in abuse and  
2     diversion. So if we became knowledgeable  
3     about certain types of diversion, then we  
4     would discuss where it might be  
5     appropriate to share that with healthcare  
6     providers so that they are aware of these  
7     types of things, these activities were  
8     going on.

9             Q.     Okay. And then this has  
10    just the same as the other slide. "This  
11    CME-related education is completely  
12    independent and separate of the  
13    promotional materials"?

14            A.     Correct.

15            Q.     Go to Slide 32, the  
16    distribution supply chain. Would this  
17    be -- this would be the responsibility of  
18    trade and supply?

19            A.     Yeah, I just need a moment  
20    to get there.

21            Q.     Oh, I'm sorry.

22            A.     All right. Are you on  
23    Slide 31?

24            Q.     32.

1           A.     32.

2                     Yes. And I'm sorry, what  
3 was your question?

4           Q.     This would be supply and  
5 trade that would deal with these issues?

6           A.     Yes.

7           Q.     But there would be oversight  
8 from the internal and the external  
9 committees?

10          A.     Well, the -- the -- as I had  
11 mentioned earlier, that the -- the groups  
12 responsible at the company for the supply  
13 chain activities or supply chain  
14 integrity would do what they do. The  
15 information that they obtained would be  
16 presented to the risk management team to  
17 have an understanding about supply chain  
18 integrity.

19          Q.     Okay. So when we take a  
20 look at the second bullet point,  
21 "Implement following measures to prevent  
22 diversion. Obtain proof of identity from  
23 customers. Maintain retrievable receipts  
24 and distribution records. Report to DEA



1 on suspicious orders. Register with DEA.  
2 And provide controls and procedures to  
3 guard against theft and diversion."

4 Would that initially be the  
5 responsibility of either supply or trade  
6 at Johnson & Johnson?

7 A. Yes. The people responsible  
8 for the supply chain, this would be some  
9 of the activities that they would  
10 undertake.

11 Q. And if there was some  
12 recognition that something had to change  
13 within -- within these responsibilities,  
14 is that something that would then be  
15 discussed with the risk management  
16 individuals and -- and some sort of a  
17 change to the risk management plan?

18 A. Well, the discussion would  
19 be within that group of what was the  
20 issue, how did they intend to address it  
21 and what had happened.

22 The -- the information of  
23 what had happened would then be  
24 communicated to the risk management team.

1 This is what happened. These were the --  
2 what they did to mitigate whatever  
3 happened, and we would be -- might -- we  
4 might be informed if something happened  
5 or not.

6 Q. And then would it be true  
7 that there would be, if there was some  
8 discussion about how to change a policy  
9 or procedure within supply and trade,  
10 would that be then discussed in the  
11 internal board as well as the external  
12 board and maybe a decision would be made  
13 and the more conservative approach taken?

14 A. Well, the -- the supply  
15 chain group would make their decisions on  
16 what they want to do. And they would  
17 communicate it to the risk management  
18 team. That would then be discussed with  
19 the -- the two groups and then the -- the  
20 internal review committee is senior  
21 management, so they would certainly be  
22 interacting with senior management from  
23 the supply chain side to come up with  
24 what needed to happen.

1                   If they needed additional  
2   information or input from individuals  
3   outside the company, then they would  
4   certainly check with the external review  
5   committee.

6           Q.       Would the external review  
7   committee be looking at this at the same  
8   time if there was some issue that came  
9   up, or would they only look at it if the  
10   internal team needed some assistance?

11          A.       It would depend on what  
12   happened. And in point of fact, we never  
13   saw this, so it's really hypothetical at  
14   this point.

15                   But depending on the nature  
16   of what had happened, if we felt we  
17   needed to get it out to everybody, then  
18   certainly as I described it here, the  
19   information would be available to both  
20   the internal review committee and the  
21   external review committee.

22          Q.       Do you recall any incident  
23   or event of any sort that -- that  
24   required that this process take place,

1     that there be a decision made by the  
2     internal board and the external board and  
3     then you sort of had to broker the -- the  
4     decisionmaking to the more conservative  
5     approach?

6             A.     We -- for activities that  
7     took place at the RM -- for the risk  
8     management team to look at, that would  
9     have been, again, discussed with the  
10    internal review committee. The external  
11    review committee, we didn't have a lot of  
12    opportunity where we needed to, but we  
13    did check with them with certain types of  
14    decisions that we wanted to make, to get  
15    their thinking and feedback for product  
16    development. That was where -- that was  
17    a major -- that was a role that they  
18    worked with us.

19            Q.     With product development?

20            A.     With certain product  
21    development decisions, yeah.

22            Q.     Product development  
23    decisions and how that would coincide  
24    with a risk management plan?

1 A. Yes.

2 Q. Was there anyone from the  
3 legal department on any of those teams?

4 A. So there was a member of the  
5 legal department on the internal review  
6 committee, the management, the management  
7 team, yes.

8 Q. And was this -- was this  
9 just called the internal review team or  
10 was it the risk management plan internal  
11 review team or?

12 A. Well, the -- this was our  
13 risk management plan, and then this would  
14 have been the internal review committee  
15 as part of that plan.

16 Q. Then if you look at  
17 Slide 33, distribution supply chain.  
18 Monitoring IMS data. Total sales from  
19 IMS versus total sales from Janssen  
20 Ortho-McNeil, as a means of assuring  
21 checks and balances. Do you see that?

22 A. Yes.

23 Q. Would this be something by  
24 either supply or trade?

1           A.     That would be something that  
2     I would assume to be the case.

3           Q.     Okay. I think I asked you  
4     before. You don't know one way or the  
5     other whether supply or trade was -- had  
6     the ability to monitor IMS data?

7           A.     I don't know.

8           Q.     The slide would suggest they  
9     could, correct?

10          A.     Yes, because -- yes.

11          Q.     If you look to Page 40.  
12     Launch promotion. First bullet.  
13     Labeling changes directly affect  
14     promotion.

15                   We talked about that. It's  
16     fairly obvious, correct?

17          A.     Yes.

18          Q.     Educational materials  
19     related to clinical trials and related  
20     products would impact on promotional  
21     activities. That's because you could  
22     only -- there -- there would be  
23     particular standards and rules you would  
24     have to go by with respect to what you

1     could -- what you could promote from  
2     clinical trials and related products,  
3     correct?

4             A.     Yes.

5             Q.     And then the third bullet  
6     point. Surveillance, distribution supply  
7     chain findings definitely will impact on  
8     promotional activities.

9                    What's meant by that?

10            A.     If we were finding that  
11     there was diversion or activities that  
12     were going on, if people were abusing the  
13     product, then we would want to make sure  
14     that there was a way through appropriate  
15     processes and means that those were  
16     addressed in materials that -- that could  
17     be discussed at a promotional venue.

18                    So the healthcare provider  
19     would become aware of the types of things  
20     that they need to look for, in talking  
21     about that.

22            Q.     So this would be -- this  
23     would be an avenue to get information out  
24     to healthcare providers about what you

1     were -- or what your company and -- and  
2     the individuals at your company were  
3     seeing with abuse and diversion?

4             A.     Yes.  There were compliant  
5     processes.

6             Q.     I'm sorry.  What does that  
7     mean, there was compliant processes?

8             A.     Well, the promotional  
9     activities done in a compliant manner,  
10    whatever those processes would be.

11            Q.     Oh, I see.  Okay.

12                   And are you familiar, as you  
13    sit here today, with any promotion --  
14    promotional materials that provided  
15    information on abuse and diversion to  
16    healthcare providers?

17            A.     So I'm currently not at the  
18    company, so I'm not aware of what types  
19    of promotional materials that they use  
20    now.

21            Q.     Were you aware of -- did it  
22    ever happen, were there promotional  
23    materials concerning abuse and diversion  
24    to healthcare providers while you were at



1 the company?

2 A. Well, the -- as part of the  
3 information that would be distributed, a  
4 product package insert would have the  
5 information around abuse and diversion of  
6 opioid analgesics and controlled  
7 substances, C-IIs.

8 Q. Do you recall any other  
9 promotional activity other than the  
10 package insert that would have provided  
11 information developed from the risk  
12 management program about abuse and  
13 diversion that could be provided to  
14 healthcare providers?

15 A. The risk management program  
16 that we had was really predominately  
17 surveillance, and during this period of  
18 time we didn't see a lot of those types  
19 of activities. So they didn't translate  
20 necessarily into promotional materials.  
21 But we wanted to make sure that we had  
22 that available if we began to become  
23 aware of it.

24 Q. Okay. So the -- the process

1 was in place, but it wasn't something  
2 that you actually saw and -- and resulted  
3 in such promotional materials?

4 A. Yes.

5 Q. And that was true -- at  
6 least that's your understanding until  
7 you -- until you left the company?

8 A. While I was still involved  
9 in promotional activities.

10 Q. You can put that exhibit  
11 away.

12 MR. LIFLAND: Where are we  
13 time-wise?

14 THE VIDEOGRAPHER: We are  
15 exactly at 37 minutes. So 7 hours  
16 1 minute.

17 MS. CONROY: Oh okay. So do  
18 you want to take a --

19 MR. LIFLAND: Yeah, let's  
20 take a break. Try to be back by  
21 10:30.

22 THE VIDEOGRAPHER: The time  
23 is 9:57 a.m. We are going off the  
24 record.

1 (Short break.)

2 THE VIDEOGRAPHER: The time  
3 is 11:05 a.m. And we are back on  
4 record.

5 - - -

6 EXAMINATION

7 - - -

8 BY MR. LIFLAND:

9 Q. Good morning, Dr. Vorsanger.

10 A. Good morning.

11 Q. I'd like to ask you just a  
12 few preliminary questions before we get  
13 into the main part of the examination  
14 regarding your responsibilities at  
15 Janssen.

16 While you were at Janssen,  
17 did you have primary responsibility for  
18 the sales of Janssen products?

19 A. No, I did not.

20 Q. Who had that responsibility  
21 at Janssen?

22 A. That would have been the  
23 sales force.

24 Q. And did you have primary

1 responsibility for the marketing of  
2 Janssen products?

3 A. No, I did not.

4 Q. And who had that  
5 responsibility?

6 A. That would have been the  
7 marketing group.

8 Q. And did you have primary  
9 responsibility for compliance, including  
10 compliance with FDA and DEA requirements?

11 A. No, I did not.

12 Q. And who had that  
13 responsibility?

14 A. Those responsibilities would  
15 have been from the compliance group.

16 Q. Let me mark as an exhibit --  
17 I don't need to mark it. It's been  
18 marked.

19 Let me just have you get out  
20 your curriculum vitae that was marked as  
21 Exhibit 2 yesterday.

22 I'd like to just go over  
23 very quickly your background and training  
24 and so feel free to refer to this, if you

1     need it. But can you give us just a  
2     general description of your education and  
3     training starting with college?

4             A.     Yes. So I attended -- I  
5     attended the State University of New York  
6     Stony Brook. I believe it's now called  
7     Stony Brook University.

8                     After I completed my B.S., I  
9     went to New York University where I  
10    completed the New York equivalent to a  
11    master's degree. And then that was  
12    continued on when I was at the City  
13    University of New York, culminating in me  
14    getting my -- and obtaining my Ph.D. from  
15    the City University of New York.

16            Q.     And what was your Ph.D. in?

17            A.     My Ph.D. was in the area of  
18    human genetics.

19            Q.     And then did you go onto  
20    medical school after that?

21            A.     I did.

22            Q.     And can you tell us about  
23    your medical school training?

24            A.     Yeah. I attended medical

1 school at the Mount Sinai School of  
2 Medicine in New York City. And after I  
3 completed my M.D. degree, I went on to do  
4 a residence -- an internship and  
5 residencies at Montefiore Hospital and  
6 Medical Center.

7 Q. And briefly, what does  
8 internal medicine entail?

9 A. So internal medicine is a  
10 medical doctor that takes general medical  
11 care and may be responsible for diseases  
12 like heart disease or lung disease and  
13 similar types of diseases.

14 Q. And did you get experience,  
15 for example, treating patients in the  
16 clinical setting?

17 A. Yes, I did.

18 Q. And emergency room setting?

19 A. I treated patients in --  
20 certainly in the emergency room and  
21 patients on the wards as well.

22 Q. And did you have any  
23 occasion during this time, and if you  
24 want to take a look at your -- we can put

1 a time frame on it. I think it's in the  
2 mid-'80s, to prescribe opioid pain  
3 relievers?

4 A. So I would have prescribed  
5 opioid pain relievers -- relievers as  
6 part of my -- my activities in the  
7 emergency room if patients came in with  
8 sprains or other types of medical  
9 conditions that would be appropriate for  
10 an opioid analgesic.

11 Q. And after your internal  
12 medicine training, did you have  
13 additional medical training after that?

14 A. I did.

15 Q. Can you describe that?

16 A. Yes. After I completed my  
17 internal medicine training, which  
18 culminated me being board-certified in  
19 internal medicine. I had gone on to do  
20 other residency in anesthesiology up in  
21 Boston at the Massachusetts General  
22 Hospital.

23 Q. And can you describe  
24 generally what's involved in an

1     anesthesiology residency?

2             A.     So I learned about the  
3     practice of anesthesia, had to administer  
4     anesthetics to people as they undergo  
5     surgical procedures, and used a variety  
6     of -- how to appropriately use a variety  
7     of different medications to perform those  
8     anesthetics.

9             Q.     And do the anesthetics  
10    include opioid products?

11            A.     Yes, they do.

12            Q.     Can you describe some of  
13    those and how they were used?

14            A.     So I have experience using  
15    intravenous fentanyl for a number of  
16    patients. Fentanyl is a potent pain  
17    medication. It's used as an analgesic as  
18    well as an anesthetic, and used  
19    intravenous morphine as well.

20            Q.     What's the difference  
21    between anesthesia and analgesia, just  
22    for my information?

23            A.     So analgesia is control of  
24    pain. Reduction in pain. And anesthesia



1 is absence of pain.

2 So when you go in for  
3 surgery and you think of patients going  
4 and getting off to sleep so they have no  
5 pain during the procedure, that would be  
6 more of an anesthesia, anesthetic.

7 Q. And you said you did your  
8 residency in anesthesia at Mass. General?

9 A. That's correct.

10 Q. And are you board certified  
11 in any area?

12 A. Yes, I am. I'm board  
13 certified as an anesthesiologist, and as  
14 I already mentioned, I'm board certified  
15 in internal medicine.

16 Q. And after your residency,  
17 where did you go to work?

18 A. So I was invited to come on  
19 staff as an anesthesiologist at  
20 Massachusetts General Hospital. I was  
21 there from 1993 to 1990 -- sorry, from  
22 1990 to 1993.

23 And in 1993 I then went on  
24 to take a private practice physician as a

1 staff anesthesiologist at Concord  
2 Hospital, in Concord, New Hampshire.

3 Q. And can -- can you describe  
4 briefly what your work entailed in those  
5 positions?

6 A. Right. So the -- most of my  
7 work involved administering anesthetics  
8 and -- and providing anesthesia for  
9 surgical procedures, both at the  
10 Massachusetts General Hospital, as well  
11 as at Concord Hospital.

12 Q. And that would include work  
13 with opioid products?

14 A. Yes, a considerable amount.

15 Q. And which ones?

16 A. Really mostly fentanyl and  
17 other fentanyl-type products. And some  
18 morphine as well.

19 Q. And what did you do after  
20 your work as an anesthesiologist?

21 A. So after my time at Concord  
22 Hospital, and I -- we discussed the years  
23 of 1993 to 1995, I transitioned over to  
24 the pharmaceutical industry and worked at

1 Astra USA.

2 Q. And briefly, what did you do  
3 for Astra?

4 A. I was a medical advisor at  
5 Astra USA, and I provided a medical  
6 expertise then for -- for a number of  
7 their local anesthetics; local  
8 anesthetics would be medications like  
9 novocaine.

10 Q. And how long were you at  
11 Astra?

12 A. I was at Astra for several  
13 years. I left Astra in -- let me -- let  
14 me just check and -- and see. I was at  
15 Astra from 1995 to 1997. And then in  
16 1997 to 2000 I worked at another company  
17 called Parexel International.

18 Q. And what was Parexel?

19 A. Parexel is a -- is a  
20 contract research organization.

21 Q. And what is a contract  
22 research organization?

23 A. A contract research  
24 organization is a company that provides

1 services to -- mostly to the  
2 pharmaceutical industry but others as  
3 well. So companies may require  
4 additional support to run clinical  
5 trials, to analyze data, et cetera. And  
6 so a contract research organization, part  
7 of their responsibilities would be to  
8 provide that information -- those  
9 services to a pharmaceutical company.

10 Q. And why did you make the  
11 change to go from the pharmaceutical  
12 company Astra to the contract research  
13 organization Parexel?

14 A. I was really interested to  
15 learn about how clinical trials are done,  
16 how are they -- how do you write a  
17 protocol well. How do you initiate a  
18 study, execute a study, analyze the data,  
19 do safety monitoring. And my feeling was  
20 that one of the best ways to do that was  
21 at a contract research organization,  
22 where you really get the whole spectrum  
23 of -- of clinical trials.

24 The other reason why I

1     wanted to go was because I had an  
2     opportunity to see how different  
3     companies perform clinical studies and  
4     how they ran them, as opposed to being at  
5     a single company, where you can learn a  
6     great deal of information, I would then  
7     have an opportunity to see how different  
8     companies conducted their clinical  
9     trials.

10           Q.     Did you have an opportunity  
11     to work with Janssen Pharmaceuticals when  
12     you were at Parexel?

13           A.     I did.

14           Q.     And can you explain what the  
15     product was that you were working on?

16           A.     Yes.    So Janssen was  
17     developing a pain control system.    The  
18     system was designed to be used in  
19     hospital for the administration of  
20     fentanyl for the treatment of  
21     postoperative pain.    And I had worked  
22     with Janssen at that time to help develop  
23     their protocols and go through study  
24     design with them as well.

1 I also advised them on  
2 another medication. I believe it was  
3 Risperdal.

4 Q. Okay. And this fentanyl  
5 system that you referred to, is that a  
6 patch system?

7 A. No. That's a liquid that  
8 would be given -- normally that -- yeah,  
9 I misspoke. That is a patch-type system.  
10 So, as opposed to IV PCA that people may  
11 have experience with where they push a  
12 button, this was a system that did not  
13 require any kind of intravenous  
14 admission, there was no IV required.

15 The patient pushed the  
16 button and the way it was set up, it  
17 would set up an electronic charge and the  
18 fentanyl would then diffuse across the  
19 scan into the bloodstream.

20 Q. Do you know whether Janssen  
21 ever brought that product to market?

22 A. Janssen did not bring the  
23 product to market as far as I know.

24 Q. And did there come a time

1     when you went to work directly for  
2     Janssen?

3             A.     Yes. I was at Parexel for a  
4     period of time, and in October of 2000 a  
5     position became available in the U.S.  
6     medical affairs group at Janssen. And I  
7     saw a -- I started working at Janssen as  
8     an employee.

9             Q.     And what kinds of products  
10    did you work on at Janssen?

11            A.     I worked on controlled --  
12    C-II controlled substances.

13            Q.     And which products?

14            A.     I worked on Duragesic, a  
15    transdermal fentanyl product, and  
16    tapentadol.

17            Q.     What was your position, what  
18    group in Janssen did you come into?

19            A.     So I was in the U.S. medical  
20    affairs group. And that had -- the  
21    functions were very similar. At one  
22    point I was also in the scientific  
23    affairs group as well. But the  
24    responsibilities were the same. And the

1 other product that I had worked on at  
2 Janssen as well, which was an opioid but  
3 not a -- not a C -- not a controlled  
4 substance at the time was tramadol.

5 Q. Who did you work with there?

6 A. I worked in the U.S. medical  
7 affairs group, and one of the people I  
8 reported into was Dr. Bruce Moskovitz. I  
9 worked with pharmacists, other  
10 physicians, a variety of different people  
11 from the company.

12 Q. And in general, what were  
13 your responsibilities in the medical  
14 affairs group?

15 A. So in the medical affairs  
16 group, our responsibility is to work with  
17 healthcare providers to understand  
18 specifically what their data needs might  
19 be, to ensure -- from our point of view,  
20 ensure safe and effective use of our  
21 compounds. So we would understand what  
22 are the types of data that they would  
23 find compelling. And I was responsible  
24 for developing protocols for clinical



1 trials. Some of my early  
2 responsibilities included working on two  
3 clinical trials that were already  
4 underway.

5 I also partnered with other  
6 individuals in the company who were doing  
7 work in the outcomes research groups,  
8 worked with the regulatory affairs group  
9 as well. And also provided medical  
10 expertise to the medical information  
11 group.

12 Q. And what about in the field  
13 of safety monitoring and surveillance?

14 A. So I was certainly partnered  
15 with the pharmacovigilance group to do  
16 safety monitoring as well, and review  
17 data on our opioid analgesics. In  
18 addition, I worked at the company to  
19 develop an acute surveillance program to  
20 monitor, as part of safety monitoring for  
21 our prescription opioid analgesics.

22 Q. You mentioned that the two  
23 Schedule II products you worked on were  
24 Duragesic and Nucynta, and I take it that

1     you worked on both -- both formulations  
2     of Nucynta, the immediate and extended  
3     release?

4             A.     Yes, that's correct.

5             Q.     And was -- was Duragesic --  
6     were they all approved products at the  
7     time you joined Janssen in 2000?

8             A.     That's right. Duragesic had  
9     been on the market since 1990 and I had  
10    joined approximately ten years later in  
11    2000.

12            Q.     And how about Nucynta, the  
13    Nucynta products?

14            A.     Now, there was discussion  
15    about Nucynta, but I was not specifically  
16    involved in that. And then Nucynta --  
17    the -- the immediate release formulation,  
18    Nucynta, which I some -- will be  
19    referring to as Nucynta IR, but it's  
20    actually called Nucynta, didn't come on  
21    the market 2000 -- until 2009.

22            Q.     And what about the  
23    extended-release product?

24            A.     The extended-release I

1 believe came on -- was available in the  
2 U.S. market two years later, in 2011.

3 Q. All right. Let's go back.  
4 You mentioned that when you started there  
5 were -- on the Duragesic product, there  
6 were some ongoing postapproval clinical  
7 trials that you worked on.

8 What did you do with regard  
9 to those?

10 A. So those studies were really  
11 wrapping up. I was involved in data  
12 collecting. Analyzing the data, looking  
13 at adverse events as part of safety  
14 monitoring, and then working on  
15 developing a publication plan to provide  
16 that information to prescribers, and  
17 others.

18 Q. Did -- did the company have  
19 a procedure or standard procedure  
20 regarding publication of data coming out  
21 of its clinical trials, postmarketing  
22 clinical trials or outcomes research?

23 A. Yes, it did.

24 MS. CONROY: Objection.

1 BY MR. LIFLAND:

2 Q. Can you describe what that  
3 was?

4 A. Yes. So there -- there was  
5 a procedure in place that the studies  
6 that were undertaken would be published  
7 and the information would be -- would be  
8 published in a number of different ways.  
9 It may be as part of a poster  
10 presentation of the clinical data. Or it  
11 may be data which would be reviewed by  
12 professional societies, peer reviewed for  
13 presentation at scientific meetings.

14 In addition, the information  
15 would be submitted to journals with peer  
16 review and published in those journals as  
17 well.

18 Q. Let me have --

19 MR. LIFLAND: I'm going to  
20 mark as Defendant's Exhibit -- do  
21 we just do it 1?

22 MS. CONROY: It's right  
23 there. It's --

24 MR. LIFLAND: Oh, okay.

1 MS. CONROY: I think it's

2 just --

3 MR. LIFLAND: Vorsanger, I'm

4 sorry.

5 MS. CONROY: Yes.

6 MR. LIFLAND: Vorsanger

7 Exhibit 13.

8 (Document marked for

9 identification as Exhibit

10 Janssen-Vorsanger-13.)

11 BY MR. LIFLAND:

12 Q. I've marked as Exhibit 13 an

13 article entitled An Observational Study

14 of Health-Related Quality of Life and

15 Pain Outcomes in Chronic Low Back Pain

16 Patients Treated With Fentanyl

17 Transdermal System.

18 Do you recognize this?

19 A. I do.

20 Q. And can you explain what it

21 is?

22 A. Yes. So there were two

23 ongoing clinical studies that I had

24 picked up when I started at Janssen in

1     October of 2000. One was a study  
2     comparing Duragesic, the transdermal  
3     fentanyl system, to OxyContin, looking at  
4     patient preference. And the other one  
5     compared Percocet to Duragesic; again,  
6     the same endpoint of patient preference.  
7     And there was a number of different  
8     outcomes, instruments, that were in both  
9     of those studies as part of the clinical  
10    trials. And this publication looks at  
11    data from both of those studies combined,  
12    looking at health-related quality of life  
13    and pain outcomes measures for those two  
14    studies.

15           Q.     And is this an example of  
16    data that Janssen submitted for  
17    publication that had been gathered in a  
18    postmarketing clinical trial?

19           A.     Yes, that's correct.

20           Q.     And you're the last listed  
21    author on that document?

22           A.     Yes.

23           Q.     And can you just briefly  
24    describe what the conclusion of this

1 analysis was?

2 A. So this, as I mentioned, the  
3 data came from two sources. We discussed  
4 that. And our conclusion was that  
5 chronic low back pain patients who  
6 chronically used short acting opioids  
7 favored -- demonstrated a tremendous  
8 health-related quality of life burden.

9 And there were favorable  
10 health-related quality of life outcomes  
11 were observed among patients who reported  
12 pain relief.

13 So people who were starting  
14 on pain medications with chronic low back  
15 pain, there's a significant amount of  
16 burden to them by having those painful  
17 conditions.

18 Q. And is this journal that --  
19 is this a peer-reviewed journal?

20 A. Yes, it is. Current Medical  
21 Research and Opinion is a peer-reviewed  
22 journal.

23 Q. Can you describe what peer  
24 review is?

1           A.     So with a peer-reviewed  
2     journal the material is prepared by  
3     individuals who may be physicians or  
4     other investigators and is sent to the  
5     journal where it's reviewed either by  
6     people with a background -- they may be  
7     physicians, scientists, Ph.D.s, et  
8     cetera, to review that to make that the  
9     quality of the articles are such and it's  
10    appropriate for the journal.

11                So it's not just accepted  
12    but it goes through a review process to  
13    ensure that the article is, as I  
14    mentioned, of sufficient quality and  
15    appropriate for the journal.

16           Q.     And you also mentioned that  
17    there is a peer review process that goes  
18    along with publishing data in poster  
19    format at annual meetings of medical  
20    societies. Can you describe that?

21           A.     Yes. So a similar type of  
22    process would be in place. Investigators  
23    who have done clinical studies and others  
24    would submit it to a professional



1 society. And they may be individuals  
2 that the professional societies called  
3 upon to review the posters for quality  
4 and content and then make a decision that  
5 that would be appropriate to display at a  
6 scientific meeting or present the  
7 information at a scientific meeting.

8 Q. You also mentioned that you  
9 worked with outcomes research, the  
10 outcomes research group at Janssen.

11 A. Yes.

12 Q. Can you describe what  
13 outcomes research is?

14 A. So outcomes research, the  
15 type of work that they do may be usual  
16 care type studies. And those would be  
17 studies to understand how patients are  
18 treated in a typical real world setting.  
19 Those studies may begin to gain  
20 information on how patients use certain  
21 types of drugs, how they function in the  
22 medical system, who are the individuals  
23 that take care of them. Those would be  
24 some of the other examples.

1                   They may look at databases  
2     and analyze those for certain types of  
3     information as well.

4                   Those studies are really  
5     quite important for us clinically. They  
6     differ from controlled clinical trials,  
7     which in some ways they have more rigor,  
8     but there are more inclusion/exclusion  
9     criteria. So the patient population is  
10    more homogenous in a controlled clinical  
11    trial as opposed to real world evidence  
12    study or the type of information that the  
13    outcomes research groups do where it's  
14    more information on other types of --  
15    different types of patients that wouldn't  
16    necessarily be included in, like, a  
17    placebo-controlled-type study.

18                Q.     Let me go back now and ask  
19    you a few more specific questions about  
20    the medications in question starting with  
21    Duragesic.

22                   What is Duragesic?

23                A.     Duragesic is a patch. And  
24    the -- and the opioid pain medication in

1 the patch, there's pain medication in the  
2 patch. It's a potent opioid called  
3 fentanyl. It's a morphine-like drug.  
4 And the medication in the patch then  
5 diffuses or goes across the skin. And  
6 then into the bloodstream and then goes  
7 around and that medication will go to the  
8 nervous system, to the brain, to provide  
9 pain control.

10 Q. And what is fentanyl?

11 A. Fentanyl is an opioid pain  
12 medication. It's a potent opioid.

13 Q. And you described -- is  
14 this, the fentanyl that's in the patch,  
15 the same medication that you described in  
16 relation to your anesthesia work?

17 A. Yes. So it's a  
18 pharmaceutical grade fentanyl. The work  
19 that I did in the operating room would be  
20 administering fentanyl intravenously.  
21 This is a -- fentanyl that's in the  
22 fentanyl patch is pharmaceutical grade  
23 fentanyl. It's prepared according to  
24 very -- very precise, very strict ways in

1 terms of it -- to be done. Yes.

2 Q. Have you heard of illegally  
3 manufactured street fentanyl?

4 A. I have.

5 Q. Is that the same thing as  
6 pharmaceutical grade fentanyl?

7 A. Those are very different.  
8 Those are made typically in an illegal  
9 laboratory. There's really no control  
10 about those types of -- that type of  
11 fentanyl. And that fentanyl can be mixed  
12 with drugs like heroin. It's the same  
13 type of illegal opioid in a manner  
14 similar to heroin.

15 Q. What are the advantages of  
16 the patch delivery or the benefits of the  
17 patch delivery system incorporated in  
18 Duragesic?

19 MS. CONROY: Objection.

20 THE WITNESS: Some of the  
21 advantages are you have  
22 pharmaceutical grade fentanyl  
23 that's in a delivery system that's  
24 administered or delivered in a

1           very controlled way.

2                       So we have a good  
3           understanding that the amount of  
4           fentanyl would be delivered to a  
5           patient over a period of time, and  
6           then for careful -- for patients  
7           that are carefully selected for  
8           appropriate use, the drug  
9           certainly has been shown to be  
10          safe and effective in that patient  
11          population.

12   BY MR. LIFLAND:

13               Q.     Are there other advantages  
14   or other benefits for the patient?

15               A.     Yes.   So the patch delivery  
16   system allows for fentanyl to be  
17   delivered up to 72 hours.   We recognize  
18   that's not true for all patients.   For  
19   some patients, a small number may require  
20   the patch to be changed in less than  
21   72 hours, in 48 hours.   And our package  
22   insert is already labeled for such.

23               Q.     What are the benefits of a  
24   72-hour delivery system?

1           A.     So if patients are using  
2     other medications, like short-acting  
3     opioids, there's a phenomena we see  
4     clinically sometimes referred to as clock  
5     watching where the patients waiting to  
6     get to the end of the dose and they're  
7     looking at their clock to see when they  
8     can get another dose of the medication.  
9     By having a delivery system that provides  
10    continuous analgesia, continuous control  
11    of the pain for a period of time,  
12    patients don't have to be preoccupied  
13    thinking about that. The medication is  
14    available for them over that period of  
15    time.

16           Q.     Are there other benefits?

17           A.     The other benefits was that  
18    there may be -- would be the design  
19    itself. Certainly we know that the  
20    controlled delivery system that we were  
21    talking about has a certain amount of  
22    opioid delivered over a period -- period  
23    of time. And that slow rate of  
24    introduction into the nervous system or

1 controlled rate into the nervous system  
2 may be a benefit insofar as people who  
3 would seek to abuse the drug or divert  
4 the system or divert it, would be less  
5 inclined to use the system because  
6 they're more interested in a quick high,  
7 quick euphoria by having it injected.

8 Q. Which patients are  
9 appropriate for Duragesic?

10 A. So Duragesic is appropriate  
11 for patients that have chronic pain that  
12 can't be treated by other medical  
13 products that might be available like an  
14 ibuprofen and other types of medications  
15 and will require an opioid analgesic for  
16 an extended period of time.

17 Q. And is there a limitation as  
18 to the kinds of chronic pain that might  
19 be treated?

20 A. No. The indication that we  
21 have is for chronic pain regardless of  
22 the cause, as long as the requirement is  
23 that they need an opioid analgesic for an  
24 extended period of time, because this is

1 a very strong medication.

2 Q. Should patients be started  
3 on Duragesic as a first line pain  
4 therapy?

5 A. No. So the requirements are  
6 that patients need to be opioid tolerant.  
7 What that means is that patients need to  
8 be on the opioid pain medications and be  
9 on a certain amount in order for them to  
10 be able to go onto start the Duragesic,  
11 working -- using the Duragesic patch.

12 Q. And you started to speak  
13 about ways in which the patch delivery  
14 system might affect the attractiveness of  
15 the product to people who want to abuse  
16 opioids.

17 A. Yes.

18 Q. Can you elaborate on that?

19 A. Yes. So for people who want  
20 to abuse opioid pain medications, the  
21 addicts and people who want to abuse it  
22 are looking for a quick high. They want  
23 to have a quick onset of the medication  
24 to get the euphoria that they're looking



1 for.

2 By the design of the system,  
3 you have a controlled-release of  
4 pharmaceutical grade fentanyl that goes  
5 in and again takes time to get what's  
6 called a steady-state where we have a  
7 blood level. So for people who want  
8 to -- again, for the fast high that we've  
9 just been talking about, this type of a  
10 system would not be desirable -- used  
11 typically by putting it on the skin.

12 If these individuals wanted  
13 to get to the fentanyl, they would have  
14 to go and break -- they would have to  
15 break in and get the fentanyl which is  
16 mixed with a gel in the Duragesic system.

17 So they would then have  
18 fentanyl and be using an uncontrolled  
19 amount of fentanyl, which could lead to  
20 overdose, respiratory depression, and  
21 death. And it's also as they administer  
22 that fentanyl they would also have other  
23 products that are in the gel, and those  
24 would be mixed with the fentanyl and

1     there could be problems with that as  
2     well.

3                     So there were really two --  
4     two ways in which the system would not be  
5     desirable to people who were addicted to  
6     opioid medications or would seek to abuse  
7     them.

8             Q.     Is there still a potential  
9     for abuse of the product?

10            A.     Yes.  It's a controlled  
11     substance, it's a C-II.  And as with  
12     other C-IIs, there is a potential for  
13     abusing the medication.

14            Q.     And when you started in the  
15     2000, 2001 time frame, did Janssen have  
16     information about the extent to which the  
17     product was being abused in the real  
18     world?

19            A.     Yes.  We had  
20     pharmacovigilance data that had been  
21     going on since the product was approved  
22     in the 1990s.  So we certainly had those  
23     as ongoing activities as well.

24            Q.     And are you familiar with a

1 report by Pinney Associates?

2 A. Yes. So that was a report  
3 that came out about a year later. It  
4 was -- maybe less. In 2001. I had  
5 started in 2000.

6 The Pinney report described  
7 the ongoing safety for Duragesic. And in  
8 fact, noted low rates of abuse and the  
9 product was well tolerated. But Pinney  
10 was aware of the fact that another  
11 delivery system for another type of  
12 patch, called the matrix patch, was being  
13 considered by different companies. And  
14 there was a concern that the matrix patch  
15 may have abusability that might be  
16 different from the reservoir or Duragesic  
17 patch.

18 Q. Did they have any  
19 conclusions as to the reservoir patch?

20 A. They concluded that the  
21 reservoir patch was safe and that there  
22 were low mentions of abuse with the  
23 reservoir system.

24 Q. Let me show you an exhibit

1     that was marked yesterday. This is also  
2     from the early 2000s. I believe it's  
3     Exhibit 9.

4                     And can you tell us again  
5     briefly what Exhibit 9 is?

6             A.     So Exhibit 9 is a copy of  
7     the summary of an advisory board that we  
8     convened in November of 2003. It was the  
9     advisory board -- a key opinion leader  
10    advisory board, defining relative abuse  
11    liability.

12            Q.     And were you -- were you  
13    involved in convening this advisory  
14    board?

15            A.     Yes, I was the  
16    representative from the company who  
17    reached out to Dr. Sacoer and Dr. Nat  
18    Katz to put this advisory board together.

19            Q.     And can you explain what was  
20    the purpose of convening this advisory  
21    board?

22            A.     Yes. So in the 2003 time  
23    frame and even before that, we were  
24    concerned about more mentions of abuse

1     that was going on in the -- in the media.

2                     We had good information at  
3     that time that the Duragesic system was  
4     safe, it was effective, and there were  
5     low mentions of -- low mentions of abuse  
6     that we had seen. Low abusability.

7                     We were thinking about  
8     developing a follow-on product to  
9     Duragesic. And one of the things we  
10    wanted to understand is what were the  
11    types of studies that would need to be  
12    done to really understand how you can  
13    characterize the abusability of a  
14    specific product. And we wanted to  
15    understand how we could differentiate our  
16    product from other types of opioid  
17    analgesics where more abuse was -- was at  
18    least being reported in the mainstream.

19                    Q.     And how did you go about  
20    selecting the people for this advisory  
21    board. And maybe begin your answer just  
22    by explaining what an advisory board is  
23    and how Janssen uses them.

24                    A.     Right. So an advisory board

1 is a meeting where a company would invite  
2 individuals, experts with certain  
3 knowledge that we wanted to learn more  
4 about a specific condition. So in this  
5 case we were very, very interested as I  
6 mentioned in understanding more about how  
7 do we talk about the different  
8 liability -- abuse liability for  
9 different compounds and how do we -- are  
10 able to see -- what type of studies would  
11 we need to have to show the FDA and  
12 others that our products that we were  
13 thinking about developing might be  
14 different from other compounds. And to  
15 ensure that we continued to have the same  
16 type of safety profile and low  
17 abusability that we had seen with the  
18 Duragesic system.

19 So we had reached out to  
20 Dr. Sacoer to help us, and -- and Dr.  
21 Katz to come up and invite the right  
22 people, and there was a system that was  
23 set up was based on individuals'  
24 background, publications, and their

1 clinical experience. We had people from  
2 all different areas that could help us  
3 begin to understand the types of studies  
4 that we would need for abuse liability.

5 Q. And if you'll turn to  
6 Page 5. Going to Page 7 of the document.

7 A. Yes.

8 Q. That -- that would be the  
9 Bates numbers that end in 462 through  
10 464.

11 A. Correct.

12 Q. Is this the list of advisors  
13 that were invited as a result of that  
14 process?

15 A. Yes, it is. We were  
16 interested, my request to Dr. Sacoer and  
17 Dr. Katz, was to have some of the best  
18 minds that we had in the U.S. to  
19 basically help us understand the types of  
20 studies that we would need. So these  
21 were the individuals, and they came from  
22 a variety of different backgrounds.

23 People from former DEA.

24 People with expertise in epidemiology.

1     Opioid abuse. We had people who were  
2     clinical trial -- trialists. People who  
3     had experience managing patients with  
4     different types of painful conditions.

5             Q.     And I think we might have  
6     skipped over. But who were Dr. Sacoer  
7     and Dr. Katz?

8             A.     So Dr. Sacoer runs a  
9     company -- ran a company at that time  
10    that convened advisory boards. And  
11    Dr. Nathaniel Katz is someone who is a  
12    pain specialist and has expertise and  
13    interest in this area of abuse as well.

14            Q.     And did the advisory board  
15    discuss the -- the data that was  
16    available at that time that reflected on  
17    the -- the abuse reports on Duragesic and  
18    the abuse for Duragesic?

19            A.     Yes. Yes, they did. That  
20    would have been an important starting  
21    point, was to get external confirmation  
22    of what we were understanding, not only  
23    from the Pinney report that we had talked  
24    about in 2001, but to really understand



1     what other experts were thinking.

2                     And the conclusion that they  
3     had come up with, which was consistent  
4     with our findings from our  
5     pharmacovigilance data and other sources,  
6     was that there were low mentions of abuse  
7     of the Duragesic system as a starting  
8     point. And certainly that was in many  
9     ways comforting to us because that was  
10    our understanding as well.

11            Q.     And if you'll turn to  
12    Page 149 of the document. Bates ending  
13    606. Is that the discussion that you  
14    were describing there?

15            A.     Yes, it is.

16            Q.     In the first sentence there  
17    it says, "We heard in the discussion over  
18    and over again the statement that we know  
19    that Duragesic has a lower abuse  
20    potential than a lot of other opioids."

21                     And then -- well, is that a  
22    statement that you agreed with?

23            A.     Yes, I do.

24            Q.     And then there are

1     several -- there's discussion of some of  
2     the indicators for that?

3             A.     Yes.

4             Q.     One is DAWN data. Can you  
5     explain what that is?

6             A.     Yes. So in response to how  
7     do we know that, there were several  
8     indicators. As you mentioned first was  
9     the DAWN data.

10                    When we do a request for  
11     specific forms of fentanyl abuse in DAWN,  
12     it -- if it was very, very low in the mid  
13     1990s, it began to creep up at the end of  
14     the '90s. And in 2001 data it showed  
15     that approximately half of the fentanyl  
16     mentions were Duragesic. But the actual  
17     totals were still very small. And when  
18     you compare that with any of the other  
19     opioids it just doesn't even belong in  
20     the same pattern.

21                    So there's one indicator.

22     The second --

23             Q.     Let me -- before you get to  
24     the second one. The statement that half

1 of the fentanyl mentioned in DAWN was  
2 Duragesic, does that indicate that the  
3 other half of the fentanyl mentions are  
4 something else?

5 A. Yes, it could be from  
6 illegal fentanyl, or if there were other  
7 formulations of fentanyl as well.

8 Q. Okay. And the second  
9 indicator?

10 A. The second indicator would  
11 be the NFLIS which shows extremely low  
12 figures suggesting that there's little or  
13 no secondary market on the street with  
14 this material of any sort. We don't have  
15 it differentiated into Duragesic versus  
16 other products.

17 Q. And is the third indicator  
18 mentioned?

19 A. Yes. The third indicator  
20 would be the toxic exposure surveillance  
21 system which tracks over two million  
22 exposures to toxic substances every year  
23 in 39 states and 3 territories, and picks  
24 up 99.8 percent of the population in the

1 U.S.

2 Q. And is this conclusion  
3 consistent with what the company saw in  
4 its routine pharmacovigilance data?

5 A. Yes, it is.

6 Q. And can you explain what  
7 that pharmacovigilance data is?

8 A. So the pharmacovigilance  
9 data is data that would be analyzed by  
10 our pharmacovigilance group, the people  
11 with expertise in understanding  
12 information, safety information that came  
13 in. And they would analyze information  
14 coming in for Duragesic, looking at  
15 adverse events such as abuse, misuse,  
16 addiction, et cetera.

17 And when those type of  
18 analysis were done by these experts at  
19 the company, they found -- their findings  
20 were consistent with what's reported  
21 here.

22 Q. Now, you mentioned that one  
23 of the purposes of this Ad Board was to  
24 discuss studies that might be important

1 or appropriate to do around a new  
2 generation product that Janssen was  
3 considering.

4 A. Yes, that's correct.

5 Q. Can you explain what that  
6 product was?

7 A. Yes. So the follow-on  
8 product that we were considering for the  
9 Duragesic system was a matrix-type  
10 system.

11 We were mindful of the  
12 Pinney report in 2001, that Pinney had  
13 raised concerns. But have indicated that  
14 they were comfortable about the safety  
15 profile and the low rates of abuse of the  
16 Duragesic system. But the 2001 report  
17 did raise concerns about a matrix-type  
18 system, which is another type of patch.  
19 It's an adhesive with this pharmaceutical  
20 grade fentanyl embedded in the adhesive.

21 So Janssen was -- was  
22 mindful of the Pinney report and  
23 developed a follow -- was thinking about  
24 developing a follow-on product. The

1 follow-on product was called AP-48. And  
2 it had a matrix-type system that I just  
3 described, but it also contained a  
4 medication called -- which was an opioid  
5 antagonist called naltrexone.

6 The way an opioid antagonist  
7 works is it blocks the effect of the  
8 opioid. The AP-48 system was set up such  
9 that if you didn't tamper with the system  
10 and just -- the design was just to put it  
11 on the skin for a person with pain, they  
12 would not be exposed to the naltrexone.  
13 They would just receive the fentanyl.  
14 But then we ran into some --

15 Q. What was the naltrexone  
16 there for?

17 A. It was there so if someone  
18 sought to abuse or divert the product and  
19 when they tampered with it the naltrexone  
20 would mix with the fentanyl and negate  
21 the effects of the opioid analgesic. So  
22 it was designed to ensure that the  
23 product would not be tampered with by  
24 people who seek to do that.

1           Q.     And was the company able to  
2     bring that product to market, the AP-48  
3     product?

4           A.     No, unfortunately not.  
5     There were some technical issues related  
6     to it. We found that there was a small  
7     amount of naltrexone that was leaking  
8     into the -- was found its way into the  
9     bloodstream to the test patients. And  
10    the company then abandoned the idea of  
11    going forward with that system.

12          Q.     And did that affect the need  
13    to do the study proposals that were  
14    discussed in this report?

15          A.     Yes, quite a lot. Because a  
16    lot of the studies, as I mentioned  
17    earlier, were designed to understand what  
18    types of studies would need to be done to  
19    differentiate that and to understand the  
20    abuse liability of a follow-on system for  
21    Duragesic. So once we saw that we were  
22    not able to develop this, then a lot of  
23    studies would not -- would not need to be  
24    done basically.

1           Q.     Did the company go forward  
2     with any studies or activities around the  
3     question of abuse after this report that  
4     we discussed here?

5           A.     Yes, we did.

6           Q.     And can you describe that?

7           A.     Yes.    So there were two  
8     studies that were done that came out  
9     directly from the advisory board designed  
10    to provide more information to us to  
11    differentiate the Duragesic system from  
12    this matrix system that we've been  
13    discussing.

14                   One study was a likability  
15    study that was done by Inflexxion.   And  
16    the likability study was designed to  
17    understand how people who would tend to  
18    abuse opioids would like different types  
19    of pain systems.   So various opioid  
20    medications were there, including the  
21    Duragesic system and a matrix system.  
22    And addicts were asked which type of --  
23    which type of opioids did they prefer,  
24    which ones did they like.



1 Both patch systems rated  
2 very low. The Duragesic system was the  
3 lowest of all the medications that were  
4 studied, and the medications were studied  
5 which were common opioid pain  
6 medications.

7 The matrix system was a  
8 little bit higher than that, but again  
9 both tend to be low on the spectrum.

10 The second study we looked  
11 at is the ease of which fentanyl could be  
12 removed from both the matrix -- a matrix  
13 system and from the Duragesic patch. And  
14 that demonstrated that there was a  
15 difference between those two delivery  
16 systems, the Duragesic and the matrix  
17 system, again, both being fentanyl  
18 delivery systems by patch.

19 And so we had this  
20 additional data that we wanted to  
21 understand that there looked like there  
22 may be a difference between the Duragesic  
23 reservoir system and the matrix system  
24 with respect to abusability.

1           Q.     Did you provide the results  
2     of these studies to the FDA?

3           A.     Yes, we did. So these two  
4     studies were shared as part of a  
5     Citizen's Petition which was shared with  
6     the FDA.

7           Q.     And in the area of  
8     monitoring, were there any changes that  
9     were made with regard to that as a result  
10    of this Ad Board?

11          A.     Yes. So as a result of the  
12    Ad Board it was clear that we wanted to  
13    begin to step up and do additional  
14    monitoring. So in the 2004 time range or  
15    thereabouts, and the years are -- I don't  
16    want to be held specifically to the  
17    years, but thereabouts, we began to  
18    institute certain pilot programs to  
19    understand how we could monitor for  
20    abuse, in addition to continuing the  
21    types of pharmacovigilance data that we  
22    had been doing since the product launch.

23                   These were what I had  
24    referred to earlier as the acute

1     surveillance, we call -- the active  
2     surveillance programs. I had looked at a  
3     number of pilot programs, working with  
4     groups like Bensinger Dupont. And  
5     knowledgeable individuals to develop  
6     types of programs.

7             Q.     And you had mentioned that  
8     the company had a concern about the  
9     matrix patch as compared to the reservoir  
10    patch.

11            A.     Yes.

12            Q.     And that information  
13    provided -- had been provided to the FDA.

14                    Did the FDA approve the  
15    introduction of matrix patches in the  
16    United States?

17            A.     Yes, they did. We were  
18    concerned from the -- some of the  
19    studies -- based on some of the studies  
20    that we talked about that having these  
21    types of patches, which would have more  
22    fentanyl in them than the Duragesic  
23    system would be coming to the U.S.  
24    market.

1                   We communicated that to FDA.

2       FDA approved those products and  
3       instituted -- had a surveillance program,  
4       a risk management plan that would be  
5       asked for the extended-release opioid  
6       analgesics.

7               Q.     And did there come a time  
8       when Janssen introduced its own matrix  
9       patch to replace the reservoir patch?

10            A.     Yes, there was.

11            Q.     And can you explain how that  
12       came about?

13            A.     Right. So what -- Janssen  
14       did introduce a matrix patch. The patch  
15       was introduced in 2008.

16                   The -- part of -- some of  
17       the reasons why the patch was introduced  
18       is we were having manufacturing  
19       difficulties with the Duragesic system,  
20       the reservoir system. And in order to  
21       fix the problem, the matrix patch would  
22       be the best way to do that, rather than  
23       try and work on fixing the reservoir  
24       system.

1                   So we felt at that time that  
2     we had enough information about the abuse  
3     of a matrix patch that we felt  
4     comfortable introducing it into the U.S.  
5     in 2008.

6                   Q.     Did the company have data at  
7     that time to look at that it didn't have  
8     before?

9                   A.     Yes.   So we had RADARS data.  
10    We became a subscriber to RADARS in 2006.  
11    And we had been working with them since  
12    that time. We actually had asked RADARS,  
13    because the generic matrix systems had  
14    come on the market around 2005 or  
15    thereabouts, to see if they could provide  
16    information to distinguish our Duragesic  
17    transdermal system from the matrix  
18    system.

19                   We certainly looked at those  
20    type of data. We tend to go back to look  
21    at our pharmacovigilance data. And we  
22    also had the information that was  
23    available for real world use of the  
24    generic matrix patches and all of that

1 data when we look at it taken together,  
2 suggested that there tended to still be  
3 low rates of abuse. And we felt  
4 comfortable at that point introducing a  
5 matrix system at that time.

6 Of course the understanding  
7 was that we would continue to do our  
8 pharmacovigilance work in addition to  
9 doing the types of active surveillance  
10 programs that we had put in place for  
11 Duragesic.

12 Q. Let me -- let's talk a  
13 little bit more about those active  
14 surveillance programs. I would like to  
15 start, I think, with the document that  
16 was marked this morning as Exhibit 12.  
17 This is a PowerPoint presentation dated  
18 May 9, 2005 entitled "Risk Management  
19 Plan For Our Products."

20 A. Yes.

21 Q. Do you recognize this  
22 document?

23 A. I do.

24 Q. And this is a document that

1     you were involved in the preparation?

2             A.     Yes.

3             Q.     And generally it describes  
4     what?

5             A.     So this was a risk  
6     management strategy that we had in place  
7     and Janssen had set in motion, a risk  
8     management plan that we would -- we would  
9     use. And this plan was put in place  
10    really as an outcome of some of the work  
11    that we had been talking about, the  
12    advisory board and some of the other data  
13    that we had to look at, prior to being  
14    required by the FDA to do such program.

15            Q.     But the FDA had requested  
16    this?

17            A.     The FDA later on had  
18    requested a risk management program and  
19    the types of work that we were looking in  
20    here was ultimately folded in that  
21    program, yes.

22            Q.     So let me -- bear with me  
23    one moment until I find the right page.  
24    Let's turn to Page 11.

1 I'm going to focus now on  
2 the surveillance pieces of this.

3 A. Yes.

4 Q. This is a flowchart that  
5 generally describes how the plan works?

6 A. Correct.

7 Q. And under surveillance there  
8 are two kinds of surveillance. The first  
9 is -- well, let's talk passive  
10 surveillance first. What does that refer  
11 to?

12 A. So the passive surveillance  
13 were the type of activities, some of  
14 which would be conducted by the  
15 pharmacovigilance group at Janssen, and  
16 they would be analyzing how adverse  
17 events that we -- might be coming into  
18 the company either through healthcare  
19 providers calling in or customer --  
20 consumers calling in.

21 Q. And the active surveillance?

22 A. Passive surveillance.

23 Q. And what about active  
24 surveillance?



1           A.     Active surveillance was --  
2     would be data that would be coming in  
3     from programs such as RADARS and later on  
4     Inflexxion.

5           Q.     And then there's a flowchart  
6     that shows, "How this gets reviewed."

7           A.     Yes.

8           Q.     And there's a reference to  
9     an internal advisory board. What was  
10    that?

11          A.     Yes, so the internal  
12    advisory board was made -- was comprised  
13    of individuals from our senior management  
14    group which would be for the various  
15    functions that would be initially taken  
16    in by the risk management team. So for  
17    example, if there was somebody from  
18    regulatory affairs on the risk management  
19    team, an internal advisory board member  
20    might be a VP level position in  
21    regulatory affairs. So these were senior  
22    leaders in the company who were  
23    responsible for, again, as part of the  
24    activities related to the product.

1           Q.     And then there is a  
2     reference to an external advisory board?

3           A.     Yes.

4           Q.     What's that?

5           A.     Yes.

6           Q.     And can you explain what  
7     that was?

8           A.     Yes.    So when I set this  
9     program up initially, the risk management  
10    team again were the individuals  
11    responsible day-to-day for caring for --  
12    ensure that the products would be used  
13    safely and effectively, providing that  
14    type of information.

15          Q.     So I guess we skipped that  
16    step.   That's the risk management team?

17          A.     Right.

18          Q.     That's the group that puts  
19    all this together when it's collected?

20          A.     Precisely.   Those would be  
21    the people who would get the initial  
22    information coming in that we would have,  
23    both -- from the various functions that  
24    they have.   And they would look at it and

1     decide if there were any types of signals  
2     or anything that may be concerning that  
3     showed that there may be issues related  
4     to abuse or -- with a compound.

5             Q.     And they give it to the  
6     internal advisory board as you just  
7     described and --

8             A.     That's correct.

9             Q.     -- the external advisory  
10    board. So you were describing what the  
11    external advisory board does?

12            A.     Yes. So the external -- it  
13    became clear that we wanted to have  
14    individuals outside the company who could  
15    help us to begin to look at those types  
16    of activities and to kind of guide us  
17    with that. So the external advisory  
18    board was created for individuals outside  
19    the company who -- who had brought with  
20    background a variety of different types  
21    of expertise.

22                    We -- as I had mentioned  
23    this morning, one individual, someone who  
24    was well knowledgeable with FDA

1 procedures, well knowledgeable with  
2 labeling and could help us with those  
3 types of activities. And I identified  
4 Cynthia -- Dr. Cynthia McCormick, who  
5 formally headed up anesthetics and  
6 critical care. And I had commented this  
7 morning that that's not the complete name  
8 of that group, but that is the group that  
9 she headed up at FDA.

10 We also had somebody who was  
11 former DEA and the person there was, as  
12 I'd mentioned, this morning was Mr. Frank  
13 Sapienza. I wanted to make sure we had  
14 a -- someone who was a pain specialist on  
15 there, who was in current clinical  
16 practice and could provide input to us  
17 about not only our own opioids but trends  
18 that might be going on in the market,  
19 that we may have to come, to make sure we  
20 have the best, most up-to-date  
21 information.

22 And Dr. James Otis who's up  
23 in Boston is a pain specialist, who was a  
24 member of the external advisory board.

1                   I -- I had also mentioned  
2     that with active surveillance, the  
3     methodology was relatively new, the  
4     passive surveillance looking at adverse  
5     events by groups like our  
6     pharmacovigilance group, those were  
7     well-established techniques. For active  
8     surveillance, there was more information  
9     that might be needed. So we had someone  
10    with expertise in signal detection  
11    methodology who could help us comment and  
12    provide a framework on what we were  
13    looking at, and Dr. Stemhagen had that  
14    role.

15                   And I also wanted to have a  
16    bioethicist who could help us with -- to  
17    make sure that we were on the right track  
18    and our decisions were kind of checked  
19    with someone outside the company to make  
20    sure that we felt that we were doing the  
21    right thing for our patients.

22                   Q.     And what was the process for  
23    them making decision, you've got these  
24    two boards who got the information?

1           A.     So the information would  
2     come in and initially be reviewed by the  
3     risk management team. And that team was  
4     comprised of people from a variety of  
5     different functions. There was somebody  
6     from medical affairs, myself was on that.  
7     We had someone from regulatory. And from  
8     a number of different functions in the  
9     company who would have had those  
10    responsibilities.

11                They would be reviewing  
12    data, it may be pharmacovigilance data or  
13    RADARS data. And decide whether we  
14    thought that there was some type of a --  
15    if there was a signal that we would then  
16    decide that that would need be shared  
17    with the internal advisory group, as well  
18    as the external advisory board group.

19           Q.     And from that process would  
20    come recommendations for action if  
21    needed?

22           A.     Yes, that's correct.

23           Q.     And was this information --  
24    well, let me ask you. How -- how often

1 did the advisory boards meet?

2 A. So the internal -- my  
3 recollection was the internal advisory  
4 board, I think we had scheduled was a  
5 quarterly meeting on a regular basis.  
6 But -- but those -- then we could convene  
7 ad hoc meetings, if there was something  
8 serious that came up.

9 So we had constant  
10 surveillance. If the RMT had noticed  
11 something, then we could convene an  
12 internal advisory board at any time. But  
13 they would -- also the plan was to have  
14 scheduled advisory boards, for updates to  
15 a quarterly basis.

16 To the external advisory  
17 board, I met with them, I think  
18 quarterly.

19 Q. And was this information  
20 also provided to the Food and Drug  
21 Administration, the -- the results of  
22 this risk management surveillance?

23 MS. CONROY: Objection.

24 THE WITNESS: So the RADARS

1 data, and the Inflexxion data,  
2 were provided to the FDA and  
3 updates on reports, yeah, so that  
4 information was provided to them.  
5 And the pharmacovigilance data  
6 that would be looked at would be  
7 part of the annual safety updates,  
8 and other types of reports that  
9 would be sent to FDA, you know,  
10 per policy.

11 BY MR. LIFLAND:

12 Q. Let me ask you to turn to --  
13 I had it a minute ago. Okay. Page 10.  
14 There's a reference here to the  
15 independent external advisory board, the  
16 structure was built on the learnings from  
17 Ultram, Ultracet, Duragesic, Concerta  
18 models. Can you explain that, please?

19 A. Yes. So Janssen had worked  
20 to create an advisory board. The -- it  
21 was -- for -- for tapentadol -- for  
22 tramadol, sorry, the independent steering  
23 committee. And that was built working  
24 with individuals with an expertise around



1 abuse and those methodologies were  
2 actually developed along with these --  
3 these individuals by Janssen for  
4 monitoring tramadol.

5 So the Ultram and Ultracet,  
6 that type of information, we had learned  
7 what are the types of methodologies that  
8 would be available.

9 The Duragesic, we had  
10 information from groups like Pinney  
11 Associates and others and had really  
12 reached out to work with them to gain  
13 knowledge from external experts in the  
14 area of abuse to kick off with that.

15 And from Concerta, which was  
16 another medication, groups like Bensinger  
17 Dupont had provided information to them  
18 as well. So we reached out to the very  
19 best people that we had with expertise in  
20 abuse in the U.S. to provide that type of  
21 information. And so the idea of an  
22 external advisory board providing that  
23 type of information to the company was  
24 one built on some behalf of some of our

1 other products.

2 Q. Let me ask you to turn to  
3 Page 25. Exhibit 12.

4 This is a slide which gives  
5 more detail on the surveillance divided  
6 into the passive and the active.

7 And passive starts with  
8 MedWatch?

9 A. Yes.

10 Q. Can you explain what that  
11 is?

12 A. So the MedWatch forms would  
13 be forms that health care providers could  
14 send in, or consumers could use to  
15 provide information on adverse events for  
16 our products. This is the information as  
17 I mentioned earlier that would be some of  
18 the work that would be analyzed by our  
19 pharmacovigilance group.

20 They, and other individuals  
21 in the company also looked at other types  
22 of information including governmental  
23 databases, DAWN, which looked at people  
24 presenting to an emergency room,

1 potentially with drug overdose. And  
2 tests and other systems as well. So  
3 those were some of the -- that was some  
4 of the information used for passive  
5 surveillance. And again I discussed, as  
6 I discussed earlier today, passive  
7 surveillance was information coming into  
8 the company. But looking here is another  
9 example of databases that we went out to  
10 look at.

11 Active surveillance was  
12 really more going out and getting  
13 information from a number of different  
14 sources.

15 Q. Do you know what these --  
16 what these three programs were that are  
17 identified here?

18 A. For active surveillance?

19 Q. Yes.

20 A. Yes. So -- so these were  
21 for survey information individuals which  
22 we described as on the ground, key  
23 informant or sentinel networks. So these  
24 would be -- key informant would be some

1 of the programs for example, that we  
2 would hear about from individuals who  
3 worked with people who abused and  
4 diverted these products and what they  
5 were hearing about the products, or other  
6 types of information. This may have come  
7 early on and from, again, people like the  
8 Bensinger Dupont program and some of the  
9 other programs as well. Former DEA or  
10 other people who were knowledgeable about  
11 abuse and the various products that were  
12 out there.

13                   We had also set up two  
14 individual programs. I wanted to make  
15 sure that any information that was coming  
16 in from the media, which may, or not  
17 necessarily have been picked up from our  
18 passive surveillance systems, we would  
19 become aware of as soon as it was  
20 available. So we had individuals  
21 searching the media looking for any  
22 mentions of our product, for Duragesic.

23                   In addition, we felt that  
24 internet monitoring would be another

1 place that we could begin to see how  
2 addicts or people who are abusing  
3 products might be discussing how they do  
4 that. And that type of monitoring would  
5 not be part of a passive surveillance  
6 program. So this is really extending our  
7 surveillance methodology to places that  
8 we were not before to get a more robust  
9 picture of how our products could  
10 potentially be abused.

11 Q. And who did the internet  
12 monitoring?

13 A. So the internet monitoring  
14 was conducted by Pinney Associates. We  
15 had reached out to them to do that.

16 Q. And when you mentioned  
17 earlier that you had started putting in  
18 place these programs after the 2003 Ad  
19 Board, is this what you were talking  
20 about?

21 A. Yes. That's correct. Yes.

22 Q. Now, I'd like to ask you to  
23 turn to Slide 30. And there is a  
24 reference here to a word on RADARS. Can

1     you explain what RADARS was and why we  
2     were talking about it at this point?

3             A.     Yes.    So RADARS is -- was  
4     set up to monitor for abuse and diversion  
5     of OxyContin initially.

6                     The -- and as I had  
7     mentioned, the -- the scientists and  
8     people who participated in RADARS who  
9     collected information around abuse were  
10    individuals, scientists who had worked on  
11    the independent steering committee for  
12    tramadol and had developed those  
13    methodologies and expertise and brought  
14    those to bear in the RADARS system. We  
15    were -- became very interested in RADARS  
16    when we learned that RADARS which had  
17    been done -- was set up by Purdue, was  
18    now being -- going to be made available  
19    through Denver Health and that other  
20    pharmaceutical companies could  
21    participate in the RADARS program.

22                     And because we had expertise  
23    and knowledge on the methodology, as I  
24    indicated, this was something -- this was

1 a program that we wanted to -- RADARS  
2 was, you know, could quantify some of  
3 these types of analysis. We were very  
4 interested more so than some of the  
5 descriptive analysis in the earlier  
6 program. So this was something that --  
7 that we were interested in.

8 I made the note here that  
9 RADARS is not a risk management program.  
10 It's something that provides information  
11 to us and -- to us. And the last point  
12 says it's a surveillance tool, part of  
13 the data risk management program that  
14 would be used.

15 So the company would have a  
16 better understanding of what RADARS --  
17 the type of information RADARS would be  
18 providing for us.

19 Q. Did the company eventually  
20 go forward with incorporating RADARS into  
21 the Duragesic surveillance?

22 A. Yes. As a matter of fact,  
23 that was done as soon as we had the -- as  
24 soon as we were able to join RADARS, we

1 did and then the Duragesic system was  
2 rolled into that. Subsequently also  
3 rolled tramadol into that, and then  
4 tapentadol after that.

5 MR. LIFLAND: It's now  
6 12:09. Would you folks like to  
7 take a break for lunch?

8 MS. CONROY: It's totally up  
9 to you. Whatever you want to do.

10 MR. LIFLAND: Why don't we  
11 do that.

12 THE VIDEOGRAPHER: The time  
13 is 12:11 p.m. We are going off  
14 the record.

15 (Lunch break.)

16 THE VIDEOGRAPHER: The time  
17 is 1:17 p.m., and we are back on  
18 the record.

19 BY MR. LIFLAND:

20 Q. Good afternoon,  
21 Dr. Vorsanger.

22 A. Good afternoon.

23 Q. I've placed before you what  
24 I have marked as Exhibit Number 14.



1 (Document marked for  
2 identification as Exhibit  
3 Janssen-Vorsanger-14.)

4 MR. LIFLAND: And the Bates  
5 number is JAN-MS-02305132. And  
6 it's -- that's a cover sheet for a  
7 natively provided file which is a  
8 PowerPoint entitled Duragesic Risk  
9 Management Overview, April 20,  
10 2007.

11 BY MR. LIFLAND:

12 Q. Do you recognize this  
13 document?

14 A. Yes, I do.

15 Q. And is it a description of  
16 the risk management plan that we were  
17 just discussing as it was being  
18 implemented in 2007?

19 A. Yes.

20 Q. And we've already gone over,  
21 I think, the various elements that are  
22 described in here. But I wanted to focus  
23 on what we left off with, which was the  
24 incorporation of the RADARS system into

1 the plan.

2 A. Right.

3 Q. And if you'll turn to  
4 page -- unfortunately it doesn't have  
5 pages. But if you flip to, it looks like  
6 it's about seven pages from the end, and  
7 you'll see there's a slide that says,  
8 "Active surveillance."

9 A. With the three bullets on  
10 it?

11 Q. Yes.

12 A. Okay.

13 Q. Okay. The first of those is  
14 RADARS, correct?

15 A. Yes.

16 Q. And you said that that was a  
17 surveillance resource that the company  
18 incorporated into the plan when it became  
19 available from Denver Health; is that  
20 correct?

21 A. That's correct.

22 Q. And if you'll turn -- that  
23 was around what time, what year?

24 A. Around 2006.

1           Q.     And I think as we saw in the  
2     earlier slide deck, RADARS had been  
3     maintained earlier as a proprietary  
4     service that was operated by Purdue?

5           A.     Yes.

6           Q.     When you incorporated RADARS  
7     into the system, did you -- did you  
8     purchase the earlier data that RADARS had  
9     collected?

10          A.     Yes.   When we started doing  
11     surveillance with RADARS for Duragesic I  
12     was interested in finding out what  
13     information, what was available, around  
14     the fentanyl products that were done  
15     prior to us starting our subscription.  
16     So we did have information that we did  
17     purchase from them.

18          Q.     And if you'll take a look at  
19     the next few slides.   Well, let's start  
20     with the next slide actually.   The one  
21     that says, "Active surveillance RADARS."

22          A.     Yes.

23          Q.     Let me make an attempt here  
24     to put it on the screen.

1                   This lists the various  
2   elements of the RADARS system. Can you  
3   give a brief explanation of what those  
4   are?

5                   A.     So the key informant network  
6   was a network I believe that was  
7   developed by Dr. Ted Cicero. And these  
8   were individuals who worked with people  
9   who abused products and they were gaining  
10   information about specific products in  
11   the form of a survey questionnaire. And  
12   those were -- those data were brought in  
13   and analyzed as part of one of the  
14   components of the RADARS system.

15                   The second one was a law  
16   enforcement network run by Dr. Inciardi.  
17   And I believe this was information  
18   collected from individuals working in law  
19   enforcement capacities from what they may  
20   have heard about drug seizures, heard  
21   other -- in areas where law enforcement  
22   became aware of different types of opioid  
23   analgesics and other medications that may  
24   have been gotten involved because of

1 illegal-type activities.

2                   The AATOD, the American  
3 Association For Treatment of Opioid  
4 Dependence looked at individuals coming  
5 in, I believe, on methadone maintenance,  
6 and having an understanding of those  
7 types -- of that type of activity and  
8 what are the -- what are the medications  
9 that those individuals may have been  
10 using and abusing, and the poison control  
11 network was part of the U.S. poison  
12 control network.

13               Q.     All right. If you can turn  
14 to the next few slides.

15               A.     By the way, we have one more  
16 that was -- that may have been added  
17 later, which is the college survey.  
18 College survey.

19               Q.     Can you explain what that  
20 is?

21               A.     The college survey, I think,  
22 looked at the use of medications by  
23 college students, not for whom the drugs  
24 were prescribed. So for recreational

1 use.

2 Q. If you could turn to the  
3 next few slides. Do these slides depict  
4 the information that you purchased as the  
5 earlier RADARS data from the period prior  
6 to 2006?

7 A. Yes. These are -- these are  
8 data coming from the different networks  
9 that we just discussed.

10 Q. All right. Let me put the  
11 first one up on the screen. This is key  
12 informant data. Can you describe here  
13 where fentanyl shows up on this?

14 A. Yes. So on this slide,  
15 fentanyl is the green line which you can  
16 see at the bottom, and captures fentanyl  
17 cases. And this would be Duragesic as  
18 well as other forms of fentanyl,  
19 including illegal fentanyl. And you can  
20 see from the time frame of the first  
21 quarter of 2002 through the first quarter  
22 of 2005, for this period of time, again  
23 it is predating our time joining the  
24 RADARS system. So these are RADARS data

1     indicating again the average number of  
2     cases of drugs and responding information  
3     for this time frame.

4             Q.     Let's look at the next  
5     slide, which is the law enforcement  
6     network data from RADARS --

7             A.     Yep.

8             Q.     -- for 2002 through 2004.  
9     Can you explain what you see there?

10            A.     Yes.   So here again, as we  
11     look at it, fentanyl is the green line,  
12     which you can see.   And there's some  
13     variation that you can see if you look at  
14     1Q '02, a little -- a little blip up and  
15     then down, and generally a fairly stable  
16     pattern which is very similar to what we  
17     had seen on the previous slide.

18            Q.     And again does this include  
19     all forms of fentanyl?

20            A.     Yes.   Same as what we had  
21     mentioned before.   It would be all forms  
22     of fentanyl including Duragesic, other  
23     forms of fentanyl, and illicit fentanyl.

24            Q.     Let's take a look at the

1 next slide, which is what you called the  
2 AATOD?

3 A. Yes.

4 Q. And I can't remember what  
5 that stands for. Maybe you can explain  
6 what the slide shows.

7 A. The AATOD was the American  
8 Association for the Treatment of Opioid  
9 Dependence. And these would be  
10 individuals presenting to methadone  
11 maintenance. And you can see the AATOD  
12 report, "Drug most commonly abused in  
13 prior month prior at admission to  
14 methadone maintenance program." N is one  
15 thousand. And you can see that -- the  
16 green once again is fentanyl. And to  
17 clarify, that would be different forms of  
18 fentanyl that would be included in that.

19 Q. And it's the -- one of the  
20 lower ones on the chart?

21 MS. CONROY: Objection.

22 THE WITNESS: Yes.

23 Buprenorphine is the lowest.

24 Palladone above is that, and



1           fentanyl would be the third.

2       BY MR. LIFLAND:

3           Q.     Turning a couple pages  
4       forward to -- well, let's look at the  
5       poison control data slide, which is a  
6       little further forward.

7           A.     Yes.

8           Q.     Keep going I think. Well,  
9       let me -- the one with the map of the  
10      United States, let's take a look at that,  
11      please.

12          A.     Okay.

13          Q.     What does this show?

14          A.     This says, "The 38 poison  
15      control centers serving over 200 million  
16      people are currently enrolling or in  
17      paperwork stage." Is that the slide that  
18      you're referring to?

19          Q.     Yeah.

20          A.     All right. So one of the  
21      things that we like very much about  
22      RADARS is that for the poison control  
23      information, we can get information down  
24      to a three digit zip code. So I was

1     talking about -- earlier this morning  
2     about quantification and being able to  
3     identify areas where we may witness  
4     abuse. And this shows a map of the  
5     United States covering the centers at  
6     that time.

7             Q.     And if you turn to the next  
8     slide, at the chart of poison control  
9     data.

10            A.     Yes.

11            Q.     Can you explain what we see  
12     there?

13            A.     Right. These are  
14     intentional exposure rated by quarter for  
15     all sites combined. And then looking at  
16     it for the first quarter of '03 to the  
17     second quarter of '05. And there are  
18     some footnotes about what originally the  
19     number of sites, et cetera, and  
20     describing what they mean by some of  
21     these compounds.

22                    The fentanyl mentions here  
23     are in the green line as we discussed.  
24     And again, what you can see, following

1 along is a stable pattern.

2 Q. And where do they -- where  
3 do they show in relationship to the  
4 others?

5 A. So if you look at the green  
6 line on this, this is the third from the  
7 bottom. The other ones would be  
8 hydromorphone, which below that, and on  
9 the line would be hydrocodone.

10 Q. Future --

11 A. And there's -- by the way,  
12 it's important when you talk about --  
13 these are rates per 100,000 population,  
14 which you have on the -- under the axis.

15 Q. And what's the importance of  
16 that?

17 A. To know what the number of  
18 people that we're talking about, per  
19 population, for the denominator.

20 Q. And if you could turn, I  
21 think, two slides down. There's a slide  
22 that's entitled "How Well Does the J&J  
23 RMP Work?"

24 A. Yes.

1           Q.     "The fentanyl-tainted heroin  
2     story." Do you remember that?

3           A.     Yes, I do.

4           Q.     Can you explain.

5           A.     Yes. I had received a call  
6     from RADARS indicating that there were  
7     mentions of fentanyl abuse in some of the  
8     major cities in the United States. And  
9     one of the questions that we -- and the  
10    report says, is we indicated that heroin  
11    addicts were dying of heroin containing  
12    fentanyl in 2006.

13                   We were concerned about the  
14    fact, was this fentanyl coming from our  
15    Duragesic patches?

16                   Our media monitoring  
17    program, which I described, and poison  
18    control, detected the signal at the  
19    initial outbreak, when they first  
20    became -- this information first became  
21    available to us.

22                   The company dispatched a  
23    former DEA -- an individual who worked at  
24    DEA to investigate it on our behalf and

1     could ascertain that the fentanyl was  
2     shown to be obtained from a clandestine  
3     lab in Mexico and was illegal fentanyl.  
4     And that fentanyl was prepared, as I  
5     mentioned earlier, and was different from  
6     the fentanyl in the Duragesic patch,  
7     different from the pharmaceutical grade  
8     fentanyl.

9                     So they were able to  
10    distinguish two types of fentanyl. This  
11    illegal fentanyl on the street was not  
12    from the Duragesic patch. And this is a  
13    really good example of how our active  
14    surveillance was able to inform us of a  
15    problem, again, rather than waiting to  
16    hear about this later on and maybe  
17    picking it up through other  
18    methodologies.

19                    MR. LIFLAND: I'm going to  
20                    mark the next exhibit.

21                    (Document marked for  
22                    identification as Exhibit  
23                    Janssen-Vorsanger-15.)

24

1 BY MR. LIFLAND:

2 Q. Dr. Vorsanger, I've marked  
3 as Exhibit 15, a document which is  
4 Bates-stamped JAN-MS-00151777 and  
5 attached is a natively provided copy of a  
6 document entitled "Duragesic (Fentanyl  
7 Transdermal System) Fourth Risk  
8 Management Plan Progress Report."

9 And I don't think we need to  
10 spend a lot of time on this, because  
11 we've already spoken about most of the  
12 aspects of the risk management plan. But  
13 just when you had mentioned that the  
14 information was provided to the FDA, do  
15 you recognize what this is?

16 A. I'm sorry. I didn't hear  
17 the last.

18 Q. Do you recognize the  
19 document?

20 A. Yes, I do.

21 Q. Can you tell us what it is?

22 A. So this is -- as you  
23 describe it, this is a plan describing  
24 the fourth risk management plan progress

1 report, and it would contain information  
2 from all the elements of the plan  
3 including information coming from our  
4 passive surveillance programs that we  
5 talked about, our active surveillance  
6 programs and other elements of the risk  
7 management plan as well.

8 Q. And if you look on the  
9 second page -- I'm sorry. It would be  
10 the first page of the actual document.  
11 It lists the various people from the  
12 company who are listed as authors of the  
13 report.

14 A. Yes, that's correct.

15 Q. Do you see that?

16 A. Yes.

17 Q. And can you quickly run down  
18 what the functions are of those people?

19 A. Yes. So Dr. Gooch was a --  
20 is a pharmacovigilance scientist.

21 Dr. Kwong, I believe, was a physician  
22 working in the pharmacovigilance group.

23 Dr. Naim, I believe, was also working in  
24 that. And Dr. Woods was a risk

1 management fellow. Dr. Moskovitz was the  
2 person to whom I reported into. He's a  
3 physician. Michael Kaufman is director  
4 of regulatory affairs. Myself. Michael  
5 Levitt was a compliance manager in the  
6 global pharmaceutical supply group. And  
7 Scott Trembley was a product director at  
8 -- in marketing at Ortho-McNeil for  
9 Duragesic.

10 Q. And this was a group that  
11 was responsible for various different  
12 elements that made up the totality of the  
13 plan?

14 A. Yes, that's correct.

15 Q. And were reports in this  
16 format sent periodically to the FDA?

17 A. Yes, they were. These were,  
18 per the FDA, a process in terms of when  
19 they wanted to receive this type of  
20 information from pharmaceutical  
21 companies.

22 Q. And let me just ask you to  
23 turn to Page 32 which describes some  
24 information that's drawn from the IMS



1 Health database.

2 A. Yes.

3 Q. Does this refresh your  
4 memory on how this information was  
5 incorporated into the risk management  
6 plan?

7 A. Right. So this was a review  
8 of IMS Health data. A company called RTI  
9 Health Solutions was retained by J&J to  
10 access the IMS Health data -- LRx  
11 database which was the database that  
12 contained this information, and provide  
13 information of different types of  
14 information.

15 If you look at the  
16 methodology it discusses how it was done.  
17 That the -- this LRx database captures  
18 approximately half of all retail  
19 transactions in the U.S. and represents  
20 data assembled from a variety of  
21 different sources including chain and  
22 independent retail pharmacies, mass  
23 merchants, grocers, and system vendors.  
24 The captive data are captured over 150

1 million unique patients and approximately  
2 a million subscribers and looked at the  
3 different types of information, study  
4 population so you can see as you go down.

5 And these provided some  
6 demographics in terms of how the products  
7 were used, who would be prescribing it,  
8 the recipients of the products, et  
9 cetera.

10 The study population  
11 described patients in the IMS LRx  
12 database were included in the current  
13 dataset for analysis if they were  
14 dispensed a prescription narcotic  
15 analgesic. And if they didn't have it  
16 during the time period they weren't  
17 included.

18 And it then talks a little  
19 bit then about the variables of interest.  
20 And there's a summary of results, talking  
21 about that as well.

22 Q. Now, the purpose of this  
23 whole plan was what?

24 A. To provide information

1 around how our product is used, to  
2 capture information from the various  
3 elements of our risk management program  
4 to ensure safe -- and our products were  
5 used safely -- safely and effectively.

6 Q. And to the best of your  
7 knowledge, what did the company see in  
8 terms of safety signals over the years  
9 that the company tracked this information  
10 using this risk management plan?

11 A. To the best of my  
12 recollection, we observed low mentions of  
13 abuse for Duragesic during the time that  
14 we -- as we were tracking it.

15 Q. We're done with it.

16 A. Okay.

17 Q. Yesterday you were asked  
18 some questions on the topic of iatrogenic  
19 addiction and what information did the  
20 company have on that subject.

21 A. Yes.

22 Q. Do you remember that?

23 MR. LIFLAND: I'm going to  
24 mark as Exhibit 16, a report

1           entitled Cumulative Review of the  
2           Iatrogenic Addiction Associated  
3           With the Use of Transdermal  
4           Duragesic Fentanyl Patch. It's  
5           dated September 6, 2006. It is  
6           Bates Number JAN-MS-02754767  
7           through 783.

8                     (Document marked for  
9           identification as Exhibit  
10          Janssen-Vorsanger-16.)

11       BY MR. LIFLAND:

12                 Q.     Dr. Moskovitz --  
13       Dr. Moskovitz.

14                     Dr. Vorsanger, can you tell  
15       me what this document is?

16                 A.     I'm sorry?

17                 Q.     Can you explain what this  
18       document is?

19                 A.     Yes. So the company had  
20       been asked by the FDA to, on April 26th  
21       of 2006, to provide comments -- FDA  
22       provided comments to the company  
23       regarding a proposal, we talked about a  
24       risk minimizations plan. And one of the

1 recommendations that had been made by the  
2 FDA was to revise the company core data  
3 sheet to reflect current data and -- and  
4 medical understanding of iatrogenic  
5 addiction.

6                   So in beginning to do that,  
7 the company went back and looked at the  
8 mentions of addiction that we had in our  
9 databases to see whether the information  
10 reflected in the company core data sheet  
11 was accurate.

12                   And in doing so, we looked  
13 at, on Table 1, if you look at the  
14 fentanyl patches exposure from the time  
15 of launch to 2005. So this was data,  
16 again, from the time the product was  
17 first introduced into the U.S.  
18 marketplace until June 2005. And when  
19 they had information from -- both from  
20 the fentanyl matrix patch, and that would  
21 have been used in Europe at the time, and  
22 the fentanyl reservoir patch that we've  
23 been speaking about.

24                   If you look at the total

1     number of patient days from which these  
2     data are derived, it's one million six  
3     hundred and eleven -- sorry,  
4     1,611,158,440 patients days. And if you  
5     look at the number of mentions of  
6     addiction that came up, the number was --  
7     a review had indicated 103 cases that  
8     were reported of drug dependence  
9     associated with chronic use of  
10    transdermal fentanyl patches.

11                   Again, that number may be  
12    underreported, but still it's a  
13    relatively low number.

14                   So the numerator being 103,  
15    and as I already indicated that number  
16    could be -- could be higher, because of  
17    the underreporting which I just commented  
18    on. But the denominator would be quite  
19    large. Again, the 1 billion 611 thousand  
20    plus patient days. And we concluded with  
21    that, that that would be a number that  
22    was quite low, and therefore, the  
23    statement about it being rare was  
24    supported by our analysis of our own

1 data.

2 MR. LIFLAND: Let me mark as  
3 the next exhibits, two articles  
4 that I believe you mentioned  
5 yesterday on this topic.

6 (Document marked for  
7 identification as Exhibit  
8 Janssen-Vorsanger-17.)

9 (Document marked for  
10 identification as Exhibit  
11 Janssen-Vorsanger-18.)

12 MR. LIFLAND: I'll mark as  
13 Exhibit 17 an article by Fishbain  
14 entitled What Percentage of  
15 Chronic Nonmalignant Pain Patients  
16 Exposed to Chronic Opioid  
17 Analgesic Therapy Developed  
18 Abuse/Addiction And/Or Aberrant  
19 Drug-Related Behaviors: A  
20 Structured Evidence-Based Review.

21 And at the same time let me  
22 mark as Exhibit 18 a Cochrane  
23 Library document from the Cochrane  
24 Library Database of Systematic

1           Reviews, entitled Long-Term Opioid  
2           Management For Chronic Noncancer  
3           Pain (Review).

4       BY MR. LIFLAND:

5           Q.     Dr. Vorsanger, are these the  
6           two articles that you mentioned yesterday  
7           in your testimony addressing the question  
8           of incidence of addiction in pain  
9           patients prescribed --

10          A.     Yes, they are.

11          Q.     -- opioid therapy?

12          A.     Yes, they are.

13          Q.     And can you, starting with  
14          the Fishbain article, just describe  
15          generally, and it can be at a high level,  
16          we can all read the articles.

17                   But just generally what the  
18          authors did for their analysis --

19          A.     Sure.

20          Q.     -- and what their conclusion  
21          was.

22                   MS. CONROY:  Objection.

23                   THE WITNESS:  So I wanted to  
24          clarify, I had said yesterday I



1           didn't have the article in front  
2           of me, the date that I had given,  
3           I want to correct now, it's  
4           actually 2008. I may have  
5           mentioned it as 2010, so we can --  
6           we can correct that now, given  
7           that the article is here.

8                     But this is an article  
9           that -- it was a review article.  
10          And what the authors did was to  
11          collect the very best information  
12          that they can on what the  
13          published literature was at the  
14          time.

15                    Again, defining the  
16          different types of studies that  
17          they were interested in looking  
18          at, abuse addiction, aberrant  
19          drug-related behavior, and people  
20          with chronic pain patients who  
21          were being treated with chronic  
22          opioid analgesia therapy.

23                    And they talk about  
24          specifically the criteria that

1           they use and which studies were  
2           included or not included,  
3           depending on the types of analysis  
4           that they wanted to do. And  
5           studies may have either been used  
6           or not used depending on the  
7           number of subjects and whether  
8           they were relevant or not.

9                     And in this first article,  
10          if you look at the results, again  
11          this is the Fishbain article I'm  
12          looking at. The reports that they  
13          had talked about a quality score,  
14          and they go in to talk about how  
15          they calculated the quality score.  
16          The quality score is greater than  
17          65 percent. And for the abuse  
18          addiction grouping there were 24  
19          studies, well over 2500 patients,  
20          with chronic -- chronic pain  
21          patients. And -- and they  
22          calculated -- exposed for a  
23          calculated abuse addiction rate of  
24          approximately 3.25 percent.

1           The second study was a study  
2           that was purported -- in -- it was  
3           reported in the Cochrane Database  
4           of Systematic Reviews from the  
5           Cochrane Library.

6           Just by way of background,  
7           the Cochrane Library, this is a  
8           very prestigious group and tends  
9           to do very careful analysis on the  
10          type of studies that -- that they  
11          have done.

12          The title of this was  
13          Long-Term Opioid Management For  
14          Chronic Noncancer Pain.

15          This was also a review  
16          article. I mentioned the senior  
17          author -- the last author is  
18          Dr. Chou. This is the article  
19          that I was talking about. And  
20          this article, again, was published  
21          in 2010. So I think that date may  
22          have been incorrect from what I  
23          had said.

24          This was a review article, a

1            compilation of what the best  
2            information they had at the time.  
3            They had certain criterias on how  
4            they looked at different types of  
5            evidence, whether they were  
6            randomized controlled clinical  
7            trial, other types of evidence,  
8            and went through and talked about  
9            it.

10                      And the main result, they  
11            said they reviewed 26 studies with  
12            27 treatment groups, for a total  
13            of 4,893 participants. They talk  
14            about the different types of  
15            opioid analgesics they had and the  
16            types of analysis that they had  
17            done looking at it.

18                      Their conclusion here was,  
19            they said, "Signs of opioid  
20            addiction were reported in  
21            0.27 percent of participants in  
22            the studies that reported that  
23            outcome."

24                      So not every study did, but

1           did those where they were looking  
2           at it.

3                   "All three modes of  
4           administration were associated  
5           with clinically significant  
6           reductions in pain."

7                   And then goes on to talk a  
8           little bit about the analgesia and  
9           some other things as well.

10                   The authors' conclusion, and  
11           I'd like to actually go down to  
12           the one with the plain language  
13           summary. I think that might be  
14           helpful for us.

15                   And this is a quote from the  
16           article. "The findings of this  
17           systematic review suggest that  
18           proper management of a type of  
19           strong pain killer, opioids, in  
20           well-selected patients with no  
21           history of substance addiction or  
22           abuse can lead to long-term pain  
23           benefit for some patients with a  
24           very small, although not zero,

1 risk of developing addiction,  
2 abuse or other serious side  
3 effects." And they talk about,  
4 "However, the evidence supporting  
5 this conclusion is weak. And  
6 long-term studies are needed to  
7 identify the patients who are most  
8 likely to benefit from treatment."

9 And I want to make sure that  
10 we're clear that weak doesn't mean  
11 bad. Weak talks about levels of  
12 evidence. And certain types of  
13 studies have stronger levels of  
14 evidence than other.

15 But the other types, even  
16 the studies that may have  
17 potentially been described here  
18 with the term "weak," may be  
19 clinically quite informative and  
20 would be of interest to the people  
21 who care for patients who are --  
22 who are prescribing these types of  
23 medications.

24 MR. LIFLAND: Let me mark as

1           the next exhibit, which will be 18  
2           (sic). This is a copy of the  
3           current labeling for Duragesic.

4                   (Document marked for  
5           identification as Exhibit  
6           Janssen-Vorsanger-19.)

7                   MR. LIFLAND: I think this  
8           is again straight from the website  
9           of the FDA. So I'll get the Bates  
10          number, but it's the current  
11          labeling.

12                   I'm sorry, 19.

13   BY MR. LIFLAND:

14           Q.     Yesterday, Doctor, you were  
15   asked some questions about the term  
16   "pseudoaddiction." You mentioned the  
17   concept is embodied in the current class  
18   labeling --

19           A.     Yes.

20           Q.     -- for Schedule II opioid  
21   pain relievers in the drug and dependence  
22   section. I wanted to point you to that  
23   section and just ask you to explain that  
24   a little bit more specifically. Page 31

1 is where that section starts.

2           A.       So on Section 9 of the  
3 product package insert, drug abuse and  
4 drug dependence, under Section 9.2, there  
5 is a discussion about drug-seeking  
6 behavior. And goes onto talk about,  
7 "Drug-seeking behavior is very common in  
8 persons with substance use disorders.  
9 Drug-seeking tactics include," and they  
10 go on to discuss what those might look  
11 like.

12                   The doctor shopping, which  
13 they go on to talk about, "Visiting  
14 multiple prescribers to obtain additional  
15 prescriptions is common among drug users  
16 and people suffering from untreated  
17 addiction.

18                   "Preoccupation with  
19 achieving adequate pain relief can be  
20 appropriate behavior in a patient with  
21 poor pain control."

22                   So while there's discussion  
23 about the types of drug-seeking behavior,  
24 some of which may be aberrant



1 drug-seeking behavior, the package insert  
2 goes on to talk about what I had just  
3 described, that sometimes preoccupation  
4 when looking for this type of pain relief  
5 can be appropriate for patients with  
6 inadequate analgesia or poor pain  
7 control.

8 And this would be an example  
9 of the description of behavior described  
10 under the term "pseudoaddiction."

11 Q. Let me switch gears now and  
12 move on to tapentadol, which is the  
13 second Schedule II product that you  
14 indicated you worked on at Janssen.

15 The brand name for  
16 tapentadol is Nucynta, in the case of the  
17 immediate-release version, correct?

18 A. Yes.

19 Q. And Nucynta ER, in the case  
20 of the extended-release version?

21 A. Correct.

22 Q. And maybe to be -- we can  
23 try to keep it straight by referring to  
24 the immediate release as Nucynta IR,

1 we'll try to keep it straight as best we  
2 can.

3 A. So we'll use that for our  
4 shorthand today, but the correct name for  
5 immediate release is Nucynta, as you  
6 indicated.

7 Q. So what were your  
8 responsibilities for Nucynta?

9 A. So I was initially  
10 responsible for the immediate release  
11 formulation. And I was involved in  
12 postapproval information related to the  
13 product. So I interacted with healthcare  
14 providers and others to understand the  
15 type of information that they would need  
16 to help ensure that our product was used  
17 safe and as prescribed.

18 And, again, working  
19 specifically with individuals, looking at  
20 the types of data they had, as I  
21 mentioned, and deciding what clinical  
22 studies might be needed. These might be  
23 controlled clinical trials. In addition  
24 working with the outcomes research group

1 as we talked about for the type of real  
2 world evidence that that group can  
3 provide to prescribers requiring or  
4 requesting this type of information,  
5 working with our epidemiology group for  
6 similar types of requests for  
7 information, our regulatory affairs  
8 group, and with our medical information  
9 group to ensure that the information that  
10 we have would be scientifically  
11 up-to-date.

12 In addition, I continued the  
13 work that I had done for Duragesic with  
14 my acute surveillance programs. So we  
15 started monitoring for abuse of Nucynta  
16 IR, Nucynta, before the product actually  
17 came on the market.

18 I was interested in  
19 understanding what I would say would be a  
20 baseline levels of abuse in the  
21 marketplace, before we were introducing  
22 an immediate release opioid.

23 So we collected that data,  
24 and RADARS provided that information, and

1     when the immediate release formulation  
2     became available and was in the U.S.  
3     marketplace, we would have that data. We  
4     can track it longitudinally.

5             Q.     Okay. What is Nucynta?

6             A.     Nucynta is a centrally  
7     acting opioid analgesic. It is an opioid  
8     analgesic. It's a controlled substance.  
9     It has -- it's -- although the exact  
10    mechanism is unknown, from the  
11    preclinical studies it's believed to have  
12    two mechanisms of action, an opioid  
13    effect like the other opioids that we had  
14    been speaking about. In addition to that  
15    it has a second mechanism which is  
16    norepinephrine reuptake inhibition. And  
17    it's believed that both those mechanisms  
18    contribute to the pain control properties  
19    for Nucynta.

20            Q.     And what did the company  
21    believe were the potential -- was the  
22    potential significance of the dual  
23    mechanism of action?

24                   MS. CONROY: Objection.

1                   THE WITNESS: So the  
2                   hypothesis was because of the dual  
3                   mechanism, that there -- and that  
4                   there may have been less -- not as  
5                   strong an opioid analgesic as  
6                   other opioid analgesics, such as  
7                   morphine or other compounds, that  
8                   we -- the hypothesis is we might  
9                   expect to see less abuse and  
10                  potentially less euphoria from  
11                  the -- again, that would certainly  
12                  need to be tested.

13       BY MR. LIFLAND:

14               Q.       And did you receive  
15               information after the product was  
16               marketed that informed that question?

17                   MS. CONROY: Objection.

18                   THE WITNESS: Yes. So we --  
19                   after the immediate release  
20                   formulation was available, again,  
21                   in the U.S. for a short period of  
22                   time, we became aware of reports  
23                   from the sales force that  
24                   healthcare providers who were

1           treating patients who had  
2           previously been treated with  
3           Oxycodone or other opioids when  
4           they were switched to Nucynta,  
5           patients initially felt that the  
6           drug wasn't working, they weren't  
7           getting an analgesic effect,  
8           although the drugs were being used  
9           as prescribed, as defined, as  
10          discussed in the product package  
11          insert.

12                    So I had said to them, do we  
13           know whether they -- when they had  
14           made this complaint or concern  
15           about the inadequate analgesia,  
16           had they actually measured levels  
17           of pain before and after using the  
18           medication?

19                    We went back and in fact  
20           they had. So they were able to  
21           report a reduction in pain  
22           intensity, which is a measure  
23           showing analgesia control, that  
24           patients were getting some kind of

1           analgesic benefit. But the  
2           patients were not experiencing  
3           euphoria that they may have  
4           perceived on some other opioids.

5                        So this was anecdotal  
6           information. But it was  
7           interesting at least in the  
8           beginning that, again, using the  
9           drug as prescribed, presumably,  
10          that we were getting these  
11          reports.

12       BY MR. LIFLAND:

13               Q.     Now, Nucynta was a new  
14          molecule, correct?

15               A.     Yes.

16               Q.     And what was the form of  
17          administration?

18               A.     It was an oral medication.

19               Q.     So it's a pill?

20               A.     It's a pill, yes.

21               Q.     And what were the  
22          indications for the product?

23               A.     So the immediate release was  
24          used for acute pain, where other form --

1 and would be appropriate -- and with the  
2 appropriate use, again, where other forms  
3 to treat a person's pain -- and I'm  
4 paraphrasing from the product label --  
5 where other forms of pain relief would  
6 not -- would not be adequate and patients  
7 would be appropriate, again, for opioid  
8 analgesic.

9                   The extended-release, again  
10 paraphrasing from the label, was that for  
11 individuals for whom lesser methods of  
12 pain control were not working in patients  
13 where it would be appropriate for opioid  
14 analgesics to be used for an extended  
15 period of time.

16               Q.     Do you remember the years in  
17 which the products were introduced?

18               A.     I believe that the immediate  
19 release form of tapentadol, Nucynta, was  
20 introduced to the U.S. market in 2009 and  
21 the extended-release was introduced in  
22 2011.

23               Q.     And were there additional  
24 steps relating to abuse or safety taken



1 with respect to the release of the  
2 extended-release indication?

3 A. Yes. So from the time the  
4 company was planning to introduce the  
5 extended-release formulation, there was  
6 an intent that that formulation would  
7 contain a coating that would have abuse  
8 deterrent properties. Understanding that  
9 we were introducing a long-acting opioid  
10 into the marketplace, we wanted to try  
11 and have that -- that needed to be a  
12 requirement to have that available.

13 Q. And was the product released  
14 with such a coating?

15 A. The product was released  
16 with this coating, yes.

17 Q. And did the company do  
18 testing related to that?

19 A. Yes, it did. The -- there  
20 was testing that was done by Grünenthal  
21 and some of their scientists to see the  
22 abusability of this -- of this abuse --  
23 this coating that may have  
24 abuse-deterrent properties. And there

1     were a number of studies that attempted  
2     to take this -- the pill and smash it  
3     with a hammer, and when doing so, it --  
4     it compressed into a format that  
5     really -- where the drug could not be  
6     easily extracted.

7                     There were studies used with  
8     something like a Waring blender, a  
9     blender, and when the -- a product was  
10    put in, the blender blades were broken.

11                    So this was resistant to the  
12    typical types of abuse methodologies that  
13    people -- addicts or people who sought to  
14    abuse, might try with this type of drug.  
15    And it could not be broken down without  
16    dental damage. So it was not something  
17    that they could bite down to -- to do  
18    that as well.

19                    MR. LIFLAND: I'm going to  
20                    mark as Exhibit 20 an article  
21                    entitled Evaluation of the Tamper  
22                    Resistant Properties of Tapentadol  
23                    Extended-Release Tablets: Results  
24                    of in Vitro Laboratory Analyses.

1 (Document marked for  
2 identification as Exhibit  
3 Janssen-Vorsanger-20.)

4 BY MR. LIFLAND:

5 Q. Have you seen this article  
6 before, Doctor?

7 A. Yes, I have.

8 Q. In fact, you are listed as  
9 an author on the article; is that  
10 correct?

11 A. Yes, that's correct.

12 Q. And can you explain what it  
13 is?

14 A. So there was an attempt to  
15 do various analysis in the laboratory to  
16 understand using, as I had mentioned  
17 previously, the types of methods that  
18 people who wanted to get opioid for abuse  
19 or -- purposes of, you know, for abuse,  
20 might do this.

21 And so they tried to crush  
22 the tablets as we talked about. They --  
23 to try to -- the -- and as I said, they  
24 used two metal spoons. Minimal

1 deformation, they'll pulverize and break  
2 it with a pill crusher.

3 Slight deformation,  
4 deformation with the standardized  
5 Pharmacopeia, breaking forces and other  
6 types of tests that went on as well.

7 Intact tablets were also  
8 completely resistant to extraction in  
9 most organic solvents tested. In eight  
10 solvents the amount of drug extracted  
11 increased with time. Hammer tablets were  
12 less resistant to extraction but required  
13 vigorous shaking over extended periods of  
14 time to release greater than half of the  
15 active ingredients.

16 So again, these were a  
17 number of different ways tested in the  
18 laboratory. And the conclusion that we  
19 had was in vitro results from tamper --  
20 tampering attempts presented here and  
21 demonstrated that tapentadol ER tablets  
22 were resistant to these forms of physical  
23 manipulation. Tapentadol ER tablets were  
24 also generally resistant to dissolution

1 in most solvents. Developing tamper  
2 resistant formulations is an important  
3 step in strategies to mitigate opioid  
4 abuse.

5 Q. And these data were  
6 published in, what's the name of the  
7 journal?

8 A. Yes, this is a peer-reviewed  
9 journal. The Journal of Opioid  
10 Management. These were published in June  
11 of 2014.

12 Q. Are you familiar with the  
13 term "REMS"?

14 A. Yes.

15 Q. What does that stand for?

16 A. I believe it's risk  
17 evaluation and mitigation strategy.

18 Q. And was there a REMS  
19 associated with Nucynta extended-release?

20 A. Yes. When -- at the time  
21 around when the product was going to be  
22 approved, the FDA had asked the company  
23 and then we had instituted a REMS for the  
24 extended-release.

1 (Document marked for  
2 identification as Exhibit  
3 Janssen-Vorsanger-21.)

4 MR. LIFLAND: I'm going to  
5 mark as Exhibit 21 a copy of a  
6 document Bates stamped  
7 JAN-MS-01489228 through, excuse  
8 me, 274, entitled Risk Evaluation  
9 and Mitigation Strategy REMS For  
10 NDA 2003533 Nucynta ER Tapentadol  
11 Tablets, dated August 25, 2011.

12 BY MR. LIFLAND:

13 Q. Do you recognize this  
14 document, Dr. Vorsanger?

15 A. Yes, I do.

16 Q. And can you explain what it  
17 is?

18 A. So this is the REMS for the  
19 Nucynta ER tablets. We talked about them  
20 being oral analgesic. It describes the  
21 goal of the REMS, the REMS elements, the  
22 medication guide, the elements to ensure  
23 safe use.

24 And then how that would be

1 implemented in the timetable for  
2 submission of assessments. And the  
3 requirements again are the type of  
4 document. It goes on to talk a little  
5 bit about a medication guide for patients  
6 in the next section.

7                   So that prescribers,  
8 healthcare professionals can communicate  
9 what Nucynta ER is, to discuss whether  
10 this might be the right drug for them,  
11 and talk about their -- talk about their  
12 medical conditions and talk about what  
13 medications they should not be taking  
14 with Nucynta ER, such as a monoamine  
15 oxidase inhibitor, MAOI, et cetera.

16                   And swallow it whole. We  
17 talked about the why that would be. It  
18 talks about some of the more common side  
19 effects that you can expect. And  
20 certain -- talking about here, it's  
21 specifically talking a little bit about  
22 constipation and talking to your doctor.

23                   The idea is, talking to your  
24 doctor about your medical conditions and

1 work with them to ensure that you're  
2 using their product safely.

3 Q. So that's the Patient  
4 Medication Guide --

5 A. Yes.

6 Q. -- and you described that's  
7 one element of the REMS.

8 A. Yes.

9 Q. What are the other elements  
10 of the REMS?

11 A. So another one talks about  
12 a -- a healthcare provider letter that  
13 talks about, which we have follows that,  
14 and talks about how to use safe and  
15 effective use of the product.

16 Q. And let me direct -- when  
17 you say a healthcare provider letter,  
18 what's that?

19 A. So these would be -- these  
20 are individuals who would be prescribing  
21 the medication for patients.

22 Q. And this would be a letter  
23 that would be sent by the company to  
24 those prescribers?



1 A. That's correct, yes.

2 Q. And does it indicate here  
3 what's included with that letter?

4 A. I'm sorry?

5 Q. Can you tell me what's  
6 included with that letter according to  
7 this?

8 A. Right.

9 Q. Take a look at the second  
10 page I think.

11 A. So it talks -- so the  
12 information again talks about the goals  
13 of the REMS. It talks about how -- the  
14 reviews, how it's contraindicated, it's  
15 not intended. In addition, what would be  
16 included in that would be full  
17 prescribing information, again to talk  
18 about safe and effective use of it.

19 It goes on to talk about the  
20 sections on safe administration on  
21 Page 18.

22 Q. Take a look at the bottom of  
23 2 and 3. Does that describe what's  
24 included in the initial mailing?

1           A.     I'm sorry.

2           Q.     The bottom of Page 2, going  
3     onto Page 3.

4           A.     Yes.   So the mailings will  
5     include the following, as I started to  
6     describe, a copy of the full prescribing  
7     information.   The ER medication guide, we  
8     talked a little bit about that.   The  
9     prescribing information.   A guide for  
10    healthcare professionals on how to use  
11    the product, and a Nucynta ER education  
12    confirmation form.

13          Q.     Okay.   Well, let's just take  
14    those one by one.   The prescribing  
15    information, is that the same thing as  
16    the package insert?

17          A.     Yes.

18          Q.     And that would be the FDA  
19    approved labeling --

20          A.     Yes.

21          Q.     -- for the product?

22          A.     Correct.

23          Q.     And then the medication  
24    guide was what you just described a few

1 moments ago?

2 A. That's correct.

3 Q. That's information for  
4 patients?

5 A. Yes.

6 Q. And then the third thing is  
7 Prescribing Nucynta ER Healthcare  
8 Professional Education Program, a Guide  
9 For Healthcare Professionals Who Intend  
10 to Prescribe Nucynta ER. And that's, I  
11 believe if you want to look at it,  
12 there's a copy of that that's included as  
13 Appendix 3 to this. Appendix 2 is the  
14 healthcare letters. Appendix 3.

15 And maybe you could explain  
16 what -- what that is and what's the  
17 intention of that.

18 A. So this was an intent to  
19 provide important information and would  
20 supplement, and be in addition to the  
21 product package insert for healthcare  
22 providers on how to use -- again, how to  
23 use the product safe and effectively.

24 It talks about the black box

1 warning for the product; you see on  
2 Page 22. Has an -- and then you see a  
3 table of contents on Page 24. General  
4 opioid uses, risks, and risk factors. It  
5 talks about Section 3, Nucynta ER risks  
6 and proper patient selection, dosing  
7 administration and patient counseling.

8 So this is a nice summary, a  
9 guide, an easy quick go-to bit of  
10 information for healthcare professionals  
11 who would be prescribing this medication  
12 for their patients.

13 Q. And the focus here is on the  
14 benefit risk information?

15 A. Correct. I'm talking about  
16 the benefits of the product as well as  
17 the risks of the product.

18 Q. What about the last piece,  
19 Appendix 4?

20 A. Appendix 4 is an educational  
21 Nucynta ER education confirmation form.  
22 And after a healthcare provider has gone  
23 through and has read the REMS, they have  
24 an option of sending this information in,

1     that they confirm that they had actually  
2     completed it. And it says, "The purpose  
3     of this form is to inform you we have  
4     read the REMS educational materials in  
5     Nucynta ER, understand the major risks  
6     associated with Nucynta ER, and know how  
7     to appropriately educate patients to whom  
8     Nucynta ER is prescribed."

9                     And these -- this would be  
10    information about the prescriber, their  
11    DEA number, their affiliation, et cetera.  
12    And this could be sent to the company for  
13    us to understand how people are using the  
14    REMS information we send.

15                    We provide free educational  
16    material around the REMS as well. So we  
17    provided a variety of different  
18    educational venues to fit in to be able  
19    to learn about the REMS.

20                    Q.     Now, going back to the cover  
21    page of the exhibit. This indicates that  
22    the REMS is specifically for Nucynta ER;  
23    is that correct?

24                    A.     Yes.

1           Q.     And how long did that remain  
2     in effect?

3           A.     This was in effect until the  
4     classwide REMS was introduced.

5           Q.     What's the classwide REMS?

6           A.     The classwide REMS was a  
7     REMS that the FDA put in place for all  
8     the extended-release opioids so that  
9     there was a commonality in terms of  
10    identifying the risks for prescribers and  
11    the other types of information that they  
12    would need.

13                    So this was a  
14    product-specific REMS, which was placed  
15    by REMS that would be used classwide.

16           Q.     Now, this REMS, as you just  
17    described it, covers the educational  
18    elements --

19           A.     Yes.

20           Q.     -- of risk management.

21                    Were there further programs  
22    the company implemented with regard to  
23    this surveillance side that you had  
24    mentioned earlier?

1           A.     Yes.

2           Q.     Can you describe those?

3           A.     So when Nucynta was getting  
4     ready -- we were -- when this product was  
5     going to be marketed we decided that we  
6     wanted additional support above and  
7     beyond what we had been doing. We had  
8     the RADARS programs running for  
9     Duragesic. We talked about that. We  
10    wanted to add programs for Nucynta so we  
11    had contracted with Inflexxion to bring  
12    on some of those programs as well.

13                   (Document marked for  
14                   identification as Exhibit  
15                   Janssen-Vorsanger-22.)

16                   MR. LIFLAND: I will mark as  
17                   the next Exhibit 22 a document  
18                   entitled "Nucynta Tapentadol  
19                   Extended-Release Fourth Safety  
20                   Surveillance Progress Report."  
21                   It's dated December 2013.

22    BY MR. LIFLAND:

23           Q.     Can you explain what this  
24    document is, Dr. Vorsanger?

1           A.     Yes.   So this is for Nucynta  
2   ER.   The fourth safety surveillance  
3   progress report, dated, as we had  
4   mentioned, the 2nd of December 2013.

5           Q.     This would be an example of  
6   a report to the FDA of the surveillance  
7   data collected for tapentadol?

8           A.     Correct.

9           Q.     And if we look at the table  
10  of contents starting on Page 8.

11          A.     It describes the elements  
12  that would be part of the surveillance  
13  plan that we have in place.

14          Q.     And those are -- those  
15  parallel pretty closely to what we've  
16  already talked about was in place or  
17  still was in place for Duragesic,  
18  correct?

19          A.     Yes.   That's correct.

20          Q.     So there would be the  
21  passive surveillance activities, the  
22  company's database of adverse event  
23  reports, the FDA's database of adverse  
24  events reports --



1 A. Yes. So --

2 Q. -- the RADARS, and then in  
3 the active there would be the RADARS  
4 system, that starts on page --

5 A. Correct.

6 Q. -- it looks like 68 of the  
7 table of contents.

8 A. Yes.

9 Q. So those are -- are those  
10 the same programs that you described  
11 previously --

12 A. Yes, they are.

13 Q. -- for Duragesic. You  
14 mentioned there was something new, the  
15 college survey program. Is that 78?

16 A. That's on Page 77 and 78,  
17 and we discussed this --

18 Q. Can you describe what that  
19 is?

20 A. Yes. So the programs that I  
21 had already described we talked about.  
22 The college survey program was an intent  
23 to expand our activities for surveillance  
24 and to try and understand abuse in

1 various groups. So here was another  
2 group where there might have been a lot  
3 of experimentation. And we wanted to  
4 understand to see whether our products  
5 would be ones that would of interest to  
6 college students.

7 So RADARS has another  
8 network, called the -- again, the college  
9 survey program. And we were able to  
10 subscribe and provide data -- get data  
11 around our drug for the college survey  
12 program.

13 Q. And if we go down further,  
14 the table of contents, there's a  
15 reference to what you just mentioned,  
16 which was the NAVIPPRO systems programs.  
17 Can you describe what those were?

18 A. Yes.

19 Q. And if you want to refer to  
20 it, they start, it looks like, on Page 80  
21 of the report.

22 A. Yeah. So we mentioned, and  
23 it's described here as part of external  
24 product-specific surveillance activities

1 involving external databases. And this  
2 is NAVIPPRO, which we were talking about.  
3 And these were reports coming in from  
4 Inflexxion, which was running the system.  
5 One was from the ASIMV, Addiction Survey  
6 Indexed Multi-Media Version. This was a  
7 computerized version of the addiction  
8 severity index. We talked a little bit  
9 about that I believe yesterday. And  
10 provided information for people coming in  
11 for opioid treatment.

12               There was also a program  
13 called the teen chat, which talked about  
14 potential abuse in a teenage group,  
15 because the data that we had before from  
16 RADARS didn't specifically address the  
17 teenage population. So by adding this  
18 dataset, we were getting more information  
19 about our products, where -- the  
20 teenagers who might be potentially  
21 abusing our product as well.

22               We also had Inflexxion, and  
23 we talked -- and the data for that, for  
24 ER, are here.

1                   We also had Inflexxion take  
2     over our internet monitoring, web-based  
3     monitoring and get us a quantification of  
4     the number of mentions of abuse of our  
5     product as discussed amongst people on  
6     the internet who might be abusing our  
7     products.

8                   So this was a nice  
9     additional monitoring on top of the other  
10    active surveillance monitoring that we  
11    had in place.

12                  Q.     And do you recall the  
13    overall results of the surveillance that  
14    were -- was conducted under this program  
15    for both the immediate release and the  
16    extended-release versions of Nucynta?

17                  A.     Yes. To the best of my  
18    recollection, when we look at the data in  
19    its totality, which would be the RADARS  
20    data, all of the Inflexxion data, the  
21    internet monitoring that was going on  
22    that we talked about, our  
23    pharmacovigilance data, all of that  
24    suggested low mentions of abuse for

1 tapentadol.

2 Q. And did you work with the  
3 people at RADARS and Inflexxion to  
4 publish that data?

5 A. Yes. There's a publication  
6 that I have, and it's entitled something  
7 like -- I'm paraphrasing on the title,  
8 31 months of RADARS data or thereabouts  
9 for the immediate release form of  
10 Nucynta.

11 Q. And did you work with the  
12 proprietors of RADARS on those  
13 publications?

14 A. Yes.

15 Q. Can you describe how that  
16 works?

17 A. So RADARS had done the  
18 analysis. And we thought it was  
19 appropriate for them, if they had agreed,  
20 that publications would be a valuable  
21 activity. This was a new opioid, and it  
22 would be of interest in the scientific  
23 community -- we agreed with it -- to  
24 publish this type of data.

1                   But they had full authorship  
2     control. We just made sure that the  
3     information around Nucynta was accurate  
4     and fair balanced, but the information  
5     and the conclusions based on the RADARS  
6     data was under the control of the RADARS  
7     authors.

8                Q.     And what were those  
9     conclusions?

10           A.     Their -- what were -- I'm  
11     sorry.

12           Q.     What were those conclusions?

13           A.     The conclusions were that in  
14     the 30 or 31 months that it had been  
15     monitored, rates of abuse were low, but  
16     very importantly that ongoing monitoring  
17     should continue.

18           Q.     And did the company do that?

19           A.     Yes, we are. So we are  
20     continuing -- well, I'm not at the  
21     company anymore, but those programs, as  
22     far as I know, are still in place and  
23     continued well after that publication.

24                   We believe that ongoing

1 monitoring is vital to -- to ensure that  
2 we understand the abuse of the product.

3 MR. LIFLAND: I have no  
4 further questions. Do you want to  
5 take a break?

6 MS. CONROY: Yeah, just five  
7 minutes.

8 MR. LIFLAND: Okay.

9 THE VIDEOGRAPHER: The time  
10 is 2:19 p.m. We are going off the  
11 record.

12 (Short break.)

13 THE VIDEOGRAPHER: The time  
14 is 2:31 p.m. We are back on the  
15 record.

16 MS. CONROY: Just for the  
17 record, I know that we have an  
18 outstanding request for  
19 Dr. Vorsanger's personnel records.  
20 And I understand that it's going  
21 to be taken up by the court. I  
22 just want to put that on the  
23 record, that we don't have that  
24 personnel file for...

1                   MR. LIFLAND: I'm happy to  
2                   meet and confer about that. And I  
3                   think we should before we take it  
4                   up with the court, but let's -- I  
5                   understand the request.

6                   MS. CONROY: I didn't mean  
7                   that we would avoid a meet and  
8                   confer. I think it's already in  
9                   the works.

10                  MR. LIFLAND: Yeah.

11                               - - -

12                               EXAMINATION

13                               - - -

14       BY MS. CONROY:

15               Q.     Dr. Vorsanger, where would I  
16               find the media reviews and the internet  
17               monitoring reports that are referenced as  
18               a part of the risk management team  
19               documents?

20               A.     Those would have been  
21               reports that would be submitted to  
22               Janssen, and so they would be at Janssen.

23               Q.     Would they have been  
24               something that you would have seen when



1       they were submitted to Janssen?

2               A.       Yes.

3               Q.       Would there be a particular  
4       department or file, how would I find  
5       those documents?

6               A.       Well, I worked in the  
7       medical affairs department, in the -- the  
8       U.S. medical affairs department in the  
9       analgesia group. I'm not sure exactly  
10      how they were filed at that point, but  
11      that's -- we were the people who were  
12      looking at that type of information.

13              Q.       Okay. So they would be --  
14      so the risk management team documents  
15      would be in the medical affairs  
16      department documents?

17              A.       Presumably. I had not gone  
18      back to look at them. But we convened  
19      those meetings and some of them we had  
20      minutes on. And your question, which was  
21      about the internet monitoring and the  
22      media monitoring, and those reports would  
23      have come in, would have been reviewed by  
24      myself, other members of my team. So

1 that would be a place to start to look.

2 I don't have an exact location to tell  
3 you.

4 Q. No, I understand. That  
5 would be a place to start.

6 A. It might be a starting  
7 point, yes.

8 Q. And you understand -- you  
9 believe that there are minutes of the  
10 quarterly meetings as well?

11 A. There -- I believe that  
12 there are minutes from the risk  
13 management team. The quarterly review  
14 that we talked about for the internal  
15 review committee, we had one meeting. I  
16 think the decision was made after we  
17 had -- we had not, as I have testified  
18 today, we had low mentions of abuse for  
19 our products. And I think the decision  
20 was made by the senior leadership that  
21 there was a reason for them to go and  
22 hear something they were interested in  
23 it, that we would agree that the people  
24 whom reported -- reported into them, who

1     were part of the risk management team,  
2     would inform them if there was something  
3     that our senior leadership needed to see.  
4     The external review committee we met  
5     with -- I met with on a quarterly basis,  
6     and I don't recall whether we kept  
7     minutes for them or not. But those  
8     meetings did take place in a Marriott in  
9     Philadelphia, as I think, I believe I had  
10    testified.

11           Q.     And approximately how many  
12    years did that go on, do you believe,  
13    where you had quarterly meetings of the  
14    external review board?

15           A.     I don't remember. That went  
16    on -- I did that for a while. And then I  
17    believe there was another physician at  
18    the company who -- who ran those -- I  
19    don't know when they ended. So I can't  
20    give you an end date.

21           Q.     Do you have a memory that  
22    there was more than one or two meetings?

23           A.     Yes. We met quarterly for a  
24    while, yes.

1           Q.     At the very end of your  
2     questioning by Mr. Lifland, you said that  
3     monitoring is vital to understand the  
4     abuse of our products.

5                     Do you recall that?

6           A.     Yes.

7           Q.     Would you also agree that  
8     understanding the risk of addiction in  
9     chronic pain patients that are prescribed  
10    Janssen's products is also vital to know?

11          A.     It's important to understand  
12    it.

13          Q.     Would you --

14          A.     Yes.

15          Q.     You would agree it's vital?

16          A.     I would -- it's quite  
17    important, yes.

18          Q.     Has Johnson & Johnson or  
19    Janssen ever been convicted of a crime?

20                     MR. LIFLAND: Object to the  
21    form of the question.

22                     THE WITNESS: I don't know.

23    BY MS. CONROY:

24          Q.     Did you go home -- did you

1 go to your home last night or did you  
2 stay nearby?

3 A. I went home.

4 Q. When you were -- you were  
5 asked some questions yesterday by me, but  
6 today by Mr. Lifland about when you were  
7 in practice and your use of opioids in  
8 the ER. Do you recall that?

9 A. Yes.

10 Q. And when you were using the  
11 opioids in the ER, was that for acute  
12 pain?

13 A. Yes.

14 Q. And when you were using it  
15 in surgeries as you were describing, that  
16 was -- you were using opioids to put  
17 people to sleep, correct?

18 A. I was using opioids both as  
19 a pain medication and as for an  
20 anesthetic. You're talking about  
21 anesthesia and analgesia.

22 Q. Yes. Did you use it as an  
23 analgesic when you were prescribing it  
24 for something other than acute pain?

1           A.     My use of it in the  
2     treatment of chronic pain was quite  
3     limited, as I had indicated and testified  
4     yesterday. Most of my experience with  
5     fentanyl was in the acute pain setting in  
6     the operating room.

7           Q.     And would it be fair to say  
8     that when you used it as an analgesic for  
9     long-term pain, that would be in a  
10    hospital setting?

11          A.     So as I had just mentioned,  
12    my use of it in the long-term -- for  
13    chronic pain was quite limited. So I did  
14    not do -- I didn't do much in the way of  
15    prescribing for that. My predominant use  
16    of the medication was in the operating  
17    room setting.

18          Q.     To put people to sleep?

19          A.     Or if they were having,  
20    let's say, a nerve block where they may  
21    have needed some supplemental pain  
22    medication and would have provided some  
23    additional pain control or some  
24    analgesia.

1           Q.     And that would have been via  
2     intravenous --

3           A.     Correct.

4           Q.     -- delivery?

5                     You also discussed with  
6     Mr. Lifland, the -- your ability when you  
7     were at Parexel to -- for want of a  
8     better term, evaluate different companies  
9     so that you could decide where you might  
10    go in the future?

11          A.     I had an opportunity to see  
12    how different companies conducted their  
13    clinical trials. And yes. And that was  
14    something that was helpful to me about  
15    where I might want to have my next  
16    employment.

17          Q.     And the companies that you  
18    were able to evaluate were Janssen and  
19    Endo; is that correct?

20          A.     I don't remember Endo.  
21    Janssen I remember best. That's where I  
22    wound up. I don't remember the other  
23    companies. But I remember looking at  
24    different types of clinical studies. I

1     talked to you about work that I had done  
2     for a cardiac medication, carvedilol. I  
3     don't remember the manufacturer of that.  
4     Different companies.

5             Q.     But the only company that  
6     you actually have a memory of is Janssen?

7             A.     The strongest memory is  
8     Janssen.

9             Q.     You marked -- we marked as  
10    Exhibit -- or Mr. Lifland marked as  
11    Exhibit 17 the Fishbain article that you  
12    discussed yesterday. I think you might  
13    want to pull it out. I'm going to ask  
14    you a couple questions about it. 17.  
15    17.

16                   THE WITNESS: I don't know  
17                   if I have it in the file here.

18                   THE COURT REPORTER: It's in  
19                   order. I put them in order.

20                   THE WITNESS: Oh, you did.  
21                   Thank you.

22                   MS. CONROY: She's way ahead  
23                   of us.

24                   MR. LIFLAND: It better be



1 in the file or else we're all --

2 THE WITNESS: That's a very  
3 good -- okay.

4 BY MS. CONROY:

5 Q. Do you know anything about  
6 the journal that this was published in,  
7 Pain Medicine?

8 A. I don't understand your  
9 question.

10 Q. Are you familiar with this  
11 publication Pain Medicine? Do you see up  
12 in the top right-hand corner, it says  
13 Pain Medicine, Volume IX?

14 A. I'm familiar with the  
15 journal Pain Medicine.

16 Q. Okay. Have you ever  
17 published in it before?

18 A. I don't remember. I don't  
19 recall.

20 Q. Okay. Are you familiar with  
21 any -- or let me -- let me ask you, do  
22 you know Dr. Fishbain?

23 A. Not personally. Just by  
24 reputation.

1 Q. What about Brandly Cole?

2 A. I don't know Brandly Cole.

3 Q. John Lewis?

4 A. I do not know John Lewis.

5 Q. Hubert Rosomoff?

6 A. I do not know that person.

7 Q. R. Steele Rosomoff?

8 A. I don't know that person

9 either.

10 Q. Do you know if they have any  
11 affiliations with any pharmaceutical  
12 companies?

13 A. I don't know if they have  
14 any affiliations with pharmaceutical  
15 companies.

16 Q. That's not something that  
17 you've looked into?

18 A. That's not -- I'm sorry. I  
19 didn't hear you, Counsel.

20 Q. That's not something that  
21 you looked into?

22 A. Typically there would be  
23 some kind of a statement talking about  
24 potential conflicts that would be listed

1     someplace in the article. So I'm aware  
2     of the fact that that type of information  
3     is called out to ensure transparency.

4             Q.     I didn't see it in this  
5     article. Do you see any kind of a  
6     callout about that in this article?

7             A.     I don't recollect that. But  
8     I didn't specifically look for it when I  
9     was reviewing the article.

10            Q.     Does that ever make a  
11     difference to you when you're using or  
12     relying on a published article, whether  
13     or not there are affiliations with  
14     different entities?

15            A.     I look to see where it's  
16     coming from. And I like to -- I look to  
17     see who is funding it. My primary focus  
18     is on the quality of the article and the  
19     conclusions based upon the -- drawn on  
20     the data.

21            Q.     You don't know who did or if  
22     this article was funded? You don't know  
23     one way or another?

24            A.     I don't have the information

1 on the article to comment.

2 Q. The very first line of the  
3 article says, "Design: This is a  
4 structured evidence-based review."

5 You are trained in clinical  
6 studies and the like. What is a  
7 structured evidence-based review?

8 A. So this is a review article,  
9 it's structured and it's discussing the  
10 design of it. And it's evidence-based  
11 looking at the types of information that  
12 you would -- to come up with the  
13 conclusions that they have.

14 Q. What does it mean structured  
15 evidence-based review?

16 A. I think what they're  
17 referring to is they have predefined in  
18 advance the nature of the review, how  
19 they collected the data, how the studies  
20 were identified, literature searchers,  
21 the search terms that we used and talked  
22 about -- and evaluated the studies in  
23 terms of the, you know, how the data were  
24 collected, which -- who was included and

1 who was not included.

2 Q. Have you ever heard that  
3 term before, structured evidence-based  
4 review?

5 A. It's not one that I'm very  
6 familiar with, but I think based on the  
7 way it was -- based on how the article  
8 was written and the information in there,  
9 I think that's what that means.

10 Q. Have you ever contacted the  
11 authors to determine if that's what they  
12 meant?

13 A. No, I have not.

14 Q. Have you ever seen any  
15 reference to a structured evidence based  
16 review in any other article that you have  
17 reviewed in your career?

18 A. I'd have to think about  
19 that.

20 Q. Are you familiar with the  
21 JAMA article that talks about the ranking  
22 of forms of evidence?

23 A. Yes.

24 Q. You're familiar with that?

1 A. I am.

2 Q. And where would you rank a  
3 structured evidence-based review?

4 A. The level of evidence would  
5 be lower than a placebo-controlled trial  
6 which represents the highest level of  
7 evidence.

8 Q. And what would this be  
9 higher than?

10 A. This might be higher than a  
11 case-control study or individual case  
12 mentions.

13 Q. So case series or an  
14 individual case?

15 A. Mm-hmm. And I believe, I  
16 think -- I have to take a look again,  
17 Counsel, but I think they talk a little  
18 bit about -- if I can look at it for a  
19 moment.

20 Q. Oh, absolutely.

21 A. They describe the -- I'm not  
22 familiar with the categorization system,  
23 but they do talk about it and various  
24 types of ways of looking at the data.

1 And they are described on Page 447.

2 Q. You are looking on the  
3 right-hand column of 447?

4 A. Correct, yes.

5 Q. This article was written in  
6 2008, it looks like. And they calculated  
7 an abuse addiction rate of 3.27 percent  
8 in the 24 -- in 24 of the studies,  
9 correct.

10 A. Let me look for the number  
11 again.

12 Q. It's right on the -- on the  
13 front page.

14 A. Yes. I'd like to find the  
15 reference.

16 Q. Sure.

17 A. Yes, 3.27 percent.

18 Q. Do you know at this time,  
19 2008, how many individuals were  
20 prescribed chronic -- opioids for chronic  
21 pain in the United States?

22 A. I don't know.

23 Q. Is that -- that information  
24 is available, correct?

1           A.     I don't know the answer to  
2     that.

3           Q.     IMS would have that  
4     information?

5           A.     Well, I don't know if they  
6     would have all the information  
7     longitudinally since 2008. They would be  
8     collecting information on people who were  
9     treated with opioid pain medications.

10          Q.     Right. And that's what I'm  
11     talking about, there would be a way --  
12     the data exists to determine approximate  
13     how many individuals in the United States  
14     have been prescribed opioid pain, opioid  
15     medication for chronic pain?

16          A.     I'm not sure what the  
17     starting point would be to be able to  
18     answer your question. When would that  
19     begin? Do you have an idea of what that  
20     might look like. So you can look at the  
21     end date, which would be 2008. But I'm  
22     not sure what you might think about for  
23     the starting point. So you can say over  
24     what period of time, since when, starting



1 from when.

2 Q. Okay. And is there a  
3 starting point for the 3.27 percent?

4 A. They talk about how they do  
5 their -- go about doing their literature  
6 searches, and that -- they go on to talk  
7 about that. And that's under methods in  
8 the methods section. They talk about the  
9 years. And so you can then begin to  
10 understand how they did it from what the  
11 starting points were. But if I -- and  
12 I'm reading on Page 447. It's -- it's  
13 kind of in the first paragraph starting  
14 with the word for. And the line would  
15 be -- I think it's about Line 13  
16 approximately.

17 Q. For details?

18 A. "For the following journals  
19 the following years were reviewed."  
20 Pain, and they talk about what years,  
21 1975 through 2006. I won't go through  
22 all of them. But they at least define a  
23 starting point of their search parameters  
24 for what years it would be.

1           Q.     And do you know what  
2     medications -- what opioid medications  
3     were available during those years?

4           A.     I'd have to look and see. I  
5     don't have it off the top of my head.

6           Q.     Do you know if the authors  
7     of this article did that?

8           A.     They would have looked for  
9     published studies that would have come  
10    out during that time period where those  
11    medications would presumably have been  
12    available in the U.S. marketplace to be  
13    able to study it.

14          Q.     Okay. But you don't know?

15          A.     I don't have the information  
16    offhand.

17          Q.     Is it anything that you ever  
18    looked at?

19          A.     I'm sorry, I don't  
20    understand the question.

21          Q.     Have you ever gone back and  
22    looked to see which drugs were available  
23    for any of these studies that were  
24    reviewed by Dr. Fishbain?

1           A.     I -- I didn't go in -- look  
2     specifically to look at the Journal of  
3     Pain, for example, for the 19 -- between  
4     1975 and 2006 to see what products they  
5     were studying specifically.

6           Q.     Have you ever collected the  
7     studies that were reviewed by  
8     Dr. Fishbain and the others?

9           A.     I'm sorry, I don't  
10    understand the question.

11          Q.     Dr. Fishbain and the other  
12    authors collected a group of studies,  
13    correct?

14          A.     Yes, they did.

15          Q.     There were 67 reports, he  
16    talks about, in the results?

17          A.     Correct.

18          Q.     Did you ever take a look at  
19    those 67 reports?

20          A.     I did not.

21          Q.     Did any one on your staff do  
22    that?

23          A.     Not to the best of my  
24    knowledge.

1           Q.     So you didn't go and -- and  
2     collect those to determine the quality of  
3     this article, this review article by  
4     Dr. Fishbain?

5           A.     To basically go back and  
6     reproduce what they did to see if I can  
7     reproduce their conclusions. Is that  
8     what you're asking me?

9           Q.     That would be part of it.

10          A.     I have not done that, no. I  
11     would have not had a reason to do that.  
12     I think the investigators did what I  
13     believe to be a thorough article which  
14     was well controlled to the extent that we  
15     talk about control and describe their  
16     methodology. If this wasn't a  
17     well-described methodology, then I would  
18     throw the article out and say I didn't --  
19     I couldn't understand how they did it,  
20     what the patient populations were, and  
21     the consequence it would not be an  
22     article that I would say I find this data  
23     compelling.

24          Q.     Did you -- do you have any

1 plans to do that, to review the 67  
2 reports?

3 A. Not specifically unless I  
4 need to go into more detail to do that,  
5 in which case it might be something that  
6 I might do. But I don't have a specific  
7 plan right now to answer your question.

8 Q. Okay. If you could take a  
9 look at Exhibit 18, which is the Cochrane  
10 analysis. Doctor, I looked through your  
11 custodial files in preparation for this  
12 deposition and I did not find a copy of  
13 either the Cochrane analysis or the  
14 Fishbain analysis.

15 Do you believe you had those  
16 available to you while you were at  
17 Janssen?

18 A. I'm not sure whether I had  
19 looked at them or not, but -- while I was  
20 at Janssen.

21 Q. So it's possible that you  
22 reviewed both the, in red, both the  
23 Fishbain and the Cochrane analysis after  
24 you left Janssen?

1           A.     Yes.

2           Q.     Is that -- is that likely  
3     that that's what happened?

4           A.     I believe the Cochrane  
5     article that we're looking at now is  
6     something that I did look at later on.

7           Q.     What about Dr. Fishbain's  
8     article?

9           A.     I don't recall that I had  
10    seen that before. But as I had commented  
11    earlier, the Cochrane Library and its  
12    systematic review of databases is of  
13    interest to me. And these are high  
14    quality analysis, they're known for that.  
15    So given my interest in long-term opioid  
16    management, in this area of noncancer  
17    pain, or noncancer -- and this may have  
18    been something that I had looked at. But  
19    I don't recall whether I specifically  
20    read it what I had read at Janssen.

21          Q.     But you have looked at it  
22    since you left Janssen?

23          A.     I have read -- looked at it  
24    very briefly, I skimmed it subsequently.

1           Q.     And as you sit here today,  
2     you have no memory of reading it while  
3     you were at Janssen, either Cochrane or  
4     Dr. Fishbain?

5           A.     I can't comment on whether I  
6     did. I said I don't recall whether I did  
7     or didn't. So that would -- that would  
8     be how I would describe it. I might  
9     have, I might not.

10          Q.     And since I didn't find any  
11     copies or references in any of your files  
12     at Janssen, from -- from your years at  
13     Janssen, would it have been your usual  
14     practice to have some reference to the  
15     articles or print them out or ask someone  
16     on your staff to do that?

17                 MR. LIFLAND: Object to the  
18     form of the question.

19                 THE WITNESS: I didn't  
20     retain a lot of them. I may have  
21     read the article, in which case  
22     afterwards I discarded it. I was  
23     not someone who routinely kept a  
24     lot of articles. So I might have

1 easily read it and then discarded  
2 it. It was not my practice to  
3 retain a lot of articles.

4 BY MS. CONROY:

5 Q. Which articles was it your  
6 practice to retain?

7 A. If I was writing a paper,  
8 then I would certainly want to have that.  
9 After the paper was -- was accepted, then  
10 I would have the references, I might hold  
11 onto it for a brief period of time. But  
12 from a document management perspective,  
13 there's so many articles that one could  
14 read that it would become problematic to  
15 collect them and even more difficult  
16 sometimes to retrieve them.

17 Q. And you are talking about  
18 both in print and electronically?

19 A. Well, electronic was  
20 slightly easier to use. But in print,  
21 yes.

22 Q. If you could turn to Page 2  
23 of the Cochrane article. And up there --  
24 well, let's look at the plain language



1 summary.

2 It says, "The findings of  
3 this systemic review suggest that proper  
4 management of a type of strong painkiller  
5 (opioid) in well-selected patients with  
6 no history of substance addiction or  
7 abuse can lead to long-term pain relief  
8 for some patients with a very small,  
9 though not zero risk of developing  
10 addiction, abuse or other serious side  
11 effects."

12 Do you see that?

13 A. Yes.

14 Q. And I think we saw in the Ad  
15 Board documents when you were speaking  
16 with a number of experts that you had  
17 selected when you were at Janssen, that  
18 in order for a patient to have no history  
19 of substance addiction or abuse, we're  
20 actually even talking about even no  
21 history of a teenager at a party  
22 having -- who is underage and drinking or  
23 taking recreational drugs, correct?

24 A. I'd need to see that

1 reference from the advisory board. If  
2 you would pull that up I would like to  
3 review it.

4 Q. I will do that. Let me ask  
5 you a couple of questions so we don't  
6 take too much time. I have it in my  
7 stack here so...

8 Do you recall -- do you  
9 recall in the Ad Board the discussion of  
10 what prior substance addiction or abuse  
11 would look like?

12 A. I don't recall the reference  
13 that you're talking about, no. So I'd  
14 like to see it.

15 Q. Okay. I will show it to  
16 you.

17 A. Yes, ma'am.

18 Q. What is your understanding,  
19 without looking at that, what is just  
20 your general understanding of a history  
21 of substance addiction or abuse?

22 A. So individuals with a  
23 history of substance abuse or addiction  
24 would certainly manifest -- or

1 potentially manifest higher rates of  
2 addiction compared to people who don't  
3 have that. And I think that was  
4 summarized nicely here.

5 Q. Give it -- what does it  
6 mean, what does it mean to have a history  
7 of substance abuse? Give me some  
8 examples.

9 A. Some -- so someone who had a  
10 history of alcohol abuse might be an  
11 example. Someone who had a history of  
12 let's say using illegally opioid  
13 analgesics, marijuana. Those most --  
14 those would be examples of history of  
15 substance abuse.

16 Q. And would it matter if  
17 someone had used marijuana in the past,  
18 would that be considered a history of  
19 abuse?

20 A. I think it would be  
21 depending on how they were using it and  
22 what the circumstances were. Some -- we  
23 know that there's some experimentation.  
24 People may use it a few times and not.

1 And I think that would be different from  
2 somebody who would use it perhaps more  
3 chronically. And really -- and then  
4 those people might be looked at  
5 differently in terms of risk. But I need  
6 to look at that in the literature to  
7 confirm what I've just said.

8 Q. Okay. Do you know  
9 whether -- do you know what criteria  
10 was -- was used in the Cochrane analysis  
11 with respect to the length of time  
12 someone may have used marijuana, whether  
13 it was recreational or more chronic?

14 A. I'm sorry, did you finish  
15 your question?

16 Q. I did finish.

17 A. Yeah, I'd have to go back  
18 and look at the article in more detail.  
19 I provided the summary today, for  
20 purposes of today, but I have to go back  
21 and look in more detail.

22 Q. Do you have any idea of the  
23 number of patients with a history of  
24 addiction or abuse in the United States?

1           A.     Do you mean -- could you  
2     clarify your question for me a little  
3     bit?

4           Q.     Well, do you have any -- do  
5     you have any ballpark idea of how many  
6     individuals there are in the United  
7     States that have a history of substance  
8     addiction or abuse?

9           A.     I'm still not understanding  
10    your question. Do you mean each  
11    category? I'm -- I'm not understanding  
12    what you're asking.

13          Q.     I'm just asking, do you have  
14    any idea -- well, let me ask -- let me  
15    break it down. Do you have any idea of  
16    the number of people in the United States  
17    who have addiction to alcohol?

18          A.     I don't have that number.

19          Q.     Do you have any idea how  
20    many individuals in the United States  
21    have used marijuana recreationally?

22          A.     I do not have that number.

23          Q.     I'll show you what's in the  
24    ad. We won't take the time to find it.

1 Can you turn to Page 24, please. Do you  
2 see there's a reference under the  
3 author's conclusions, there is a  
4 reference here in the -- kind of in the  
5 middle, "Because most studies screened  
6 out potential participants with histories  
7 of substance abuse or addiction, the  
8 rates of addiction reported in these  
9 studies are only generalizable to  
10 patients without a history of  
11 addictive/abusive behaviors."

12 Do you see that?

13 A. Yes. I'd like to read a  
14 little bit above and beyond, if I can.  
15 But I do see that. If you can give me  
16 one moment, please.

17 Q. Yeah. Take your time.

18 A. Yes, I see that.

19 Q. Do you agree with that  
20 statement?

21 A. I agree with the statement  
22 that most studies screen out potential  
23 participants with substance abuse.

24 Q. Do you agree that the rates

1 of addiction reported in these studies  
2 are only generalizable to patients  
3 without a history of addictive/abusive  
4 behaviors, or do you believe they could  
5 be used more generally than that?

6 A. Can you explain what you  
7 mean by used more generally?

8 Q. Well, do you agree with the  
9 statement as it's written?

10 A. We're talking about  
11 iatrogenic addictions. So are you  
12 talking about addiction in general, or  
13 are you talking about iatrogenic  
14 addiction?

15 Q. What do you understand this  
16 study to be talking about?

17 A. They're talking about  
18 iatrogenic addiction.

19 Q. So do you agree --

20 A. But your question was about  
21 it being generalizable. I don't know if  
22 you're talking about addiction in general  
23 or iatrogenic addiction. That's why I  
24 asked the question.

1           Q.     If you take a look at the  
2     sentence in the author's conclusion, I'm  
3     asking if you agree with that sentence.

4           A.     Yes, I do.

5           Q.     A little bit further down it  
6     says, after the Fishbain reference, it  
7     says, "Given the complexity of  
8     definitively diagnosing opioid addiction  
9     and in the interest of capturing the  
10    overall effect of opioid therapy on the  
11    quality of life, we sought to analyze  
12    health-related quality of life outcomes  
13    in this review." And they say, "See  
14    Ballantyne 2006."

15                   Do you see that?

16          A.     Yes.

17          Q.     Do you know Dr. Ballantyne?

18          A.     I do.

19          Q.     How do you know her?

20          A.     Her and I worked together at  
21    Mass General.

22          Q.     Are you in contact with her?

23          A.     I am not.

24          Q.     Were you while you were at



1 Janssen?

2 A. No. I might have seen her  
3 in a meeting once to say hello, but I was  
4 not in contact with her.

5 Q. Have you read her 2006  
6 article?

7 A. I don't recall. I might  
8 have.

9 Q. Doctor, the 2003 Ad Board  
10 that you worked on, that set out a wide  
11 spectrum of possible clinical trials and  
12 outcome research that could be done at  
13 Janssen, correct?

14 A. Yes.

15 Q. And AP 48 was just -- was  
16 just one area that could use some further  
17 research, correct?

18 A. Yes.

19 Q. One of the other areas was  
20 studies that could determine the risk of  
21 iatrogenic addiction, correct?

22 A. I believe that was another  
23 study that could -- there was a  
24 discussion about that.

1           Q.     And there was some -- there  
2     was some, for want of a better word,  
3     fleshing out of what that type of a study  
4     would look like, what the criteria might  
5     be?

6           A.     There was discussion about  
7     what potential study might look like.

8           Q.     And there were studies  
9     discussed to determine the best screening  
10    methods for patients to minimize misuse  
11    with respect to taking opioids for  
12    chronic pain?

13          A.     Yes. I believe there was  
14    discussion on that.

15          Q.     And there was discussion  
16    about studies to determine the rate and  
17    type of misuse and abuse in chronic pain  
18    populations using the addiction survey  
19    index. Do you recall those?

20          A.     There was discussion by the  
21    participants about that, yes.

22          Q.     And part of the two-day Ad  
23    Board meeting was, not only was there  
24    discussion -- and I think they were

1     called icebreakers, where there was  
2     discussion with the experts and yourself  
3     and other -- other individuals from  
4     Janssen. But then there was some  
5     breakout sessions where the experts in  
6     particular areas worked out what a study  
7     would look like. They did a work plan  
8     for a study?

9             A.     Preliminary discussion on  
10    design. The studies weren't powered  
11    statistically, to the best of my  
12    knowledge, to how large they would be.  
13    And the endpoints were hypothetical  
14    endpoints. And those were not, to the  
15    best of my knowledge, validated endpoints  
16    in clinical trials which would need --  
17    would have needed to have been done to  
18    use them to make the conclusions.

19            Q.     Well, certainly. But the  
20    design of what those studies could look  
21    like was discussed, correct?

22            A.     Potential design, yes.

23            Q.     And that was the same for  
24    the AP 48 studies. The design was

1 discussed, but the endpoints had not been  
2 validated at that point?

3 A. No. But I don't recall  
4 whether we had statistical discussions to  
5 calculate the number of patients that  
6 would be needed to address those  
7 endpoints.

8 Q. Do you think you did for AP  
9 48 at that time?

10 A. Not at the Ad Board.

11 Q. Right. And at the Ad Board,  
12 you had not worked out any of those  
13 statistics?

14 A. Correct, because the goal of  
15 the Ad Board was to understand the types  
16 of information that we would need to have  
17 in a -- in a clinical trial to be able to  
18 make the types of statements we had  
19 around abuse liability for the compound.

20 Q. Correct. And that's why you  
21 were looking at the risk of iatrogenic  
22 addiction and screening methods and  
23 studies to look at the rate of misuse in  
24 the chronic pain population, using an

1 addiction survey index, as well as  
2 likability studies and tamper issues with  
3 AP 48, correct?

4 A. Yes.

5 Q. So the -- the discussions at  
6 the Ad Board in November of 2003 had  
7 broad applicability to all of Janssen's  
8 opioid products, correct?

9 MR. LIFLAND: Object to the  
10 form of the question.

11 THE WITNESS: I'm sorry. I  
12 don't -- really, I don't  
13 understand the question.

14 BY MS. CONROY:

15 Q. The Ad Board was not set up  
16 to just discuss issues with respect to  
17 iatrogenic addiction in AP 48, it would  
18 have addressed those issues across all of  
19 Janssen's opioid products?

20 A. But we would have had  
21 information on iatrogenic addiction for  
22 Duragesic from the analysis that I  
23 presented -- that was later. That was in  
24 2006. But we did have information on

1 patient exposures. We did have  
2 information from our pharmacovigilance  
3 group on the number of reports. And I  
4 did acknowledge that that number may be  
5 low.

6                   So there were data being  
7 compiled on patient exposures and a risk  
8 of a addiction. So iatrogenic addiction  
9 was something that was being monitored in  
10 the sense of knowing how many patients  
11 were getting addicted based on reports  
12 people were having. So those were in --  
13 for in-line marketed products we would  
14 have had that information. For products  
15 that were in development however, the  
16 analysis would necessarily have to be  
17 different because we didn't have actual  
18 exposures.

19               Q.     You discussed those -- those  
20 data points at the Ad Board, correct?

21               A.     Well, we did. But those  
22 were for clinical studies for products  
23 that were in development. Not for actual  
24 products. So if I understand your

1 question, Counsel, you said, wouldn't  
2 that have been something that would have  
3 been used for all the Janssen products.  
4 And my response would be no, not for the  
5 marketed products. Those are  
6 methodologies that could be used for  
7 product in development.

8 Q. Well, you did go forward  
9 with the studies with respect to the  
10 surveillance, such as RADARS and some of  
11 the -- and the Inflexxion data? That  
12 wasn't just for AP 48?

13 A. No. That's different,  
14 right. We were talking about -- we  
15 provided -- we were looking at iatrogenic  
16 addiction with our pharmacovigilance  
17 data, and I presented the results from  
18 2006.

19 We were absolutely doing  
20 abuse surveillance with our RADARS and  
21 subsequently our Inflexxion data.

22 Q. So you don't believe that  
23 the studies that were discussed at the Ad  
24 Board concerning iatrogenic addiction or

1 screening methods for patients would have  
2 any applicability, for example, to a  
3 Duragesic patient?

4 A. No, I didn't make that  
5 statement. I made -- the statement that  
6 I made was for marketed products and the  
7 different analysis that would need to be  
8 done. And the -- not -- that only the  
9 studies that were recommended during our  
10 advisory board would be used.

11 We had actual data on  
12 patients receiving the product. And we  
13 used that data to make certain  
14 assumptions. And those -- as I testified  
15 this morning, those rates were low, and  
16 we were able to be confident that the  
17 information that we had presented that  
18 was in the package insert was correct.

19 Q. So by 2006 then, you believe  
20 that you did not need to do any further  
21 investigation or study with respect to  
22 the rates of iatrogenic addiction --

23 A. No, I --

24 Q. -- in chronic pain patients



1 taking --

2 A. No.

3 Q. -- Janssen opioids?

4 A. I don't believe I testified  
5 to that. I think what I had testified  
6 was we were interested in doing  
7 monitoring on an ongoing basis. We felt  
8 it was appropriate that our medications  
9 be monitored continually. So we were in  
10 a position that using the similar types  
11 of data that we reported to FDA in 2006,  
12 that that type of monitoring certainly  
13 can be done at any point in time, where  
14 we would look at our mentions of -- that  
15 we received of abuse and look at the  
16 number of patient days exposure, similar  
17 to what I had presented earlier.

18 Q. And do you believe that that  
19 data tracks iatrogenic addiction?

20 A. Yes. These would have been  
21 exposures. So these would have been --  
22 the data that we're talking about that I  
23 presented from our 2006 study that we  
24 submitted to FDA would have been

1 iatrogenic addiction because there --  
2 patient exposures, there were patients  
3 treated with transdermal fentanyl, either  
4 for the matrix system or the reservoir  
5 system as I presented earlier today.

6 Q. What about Nucynta? Do you  
7 have accurate data with respect to  
8 iatrogenic addiction rate?

9 A. I don't know if those data  
10 were captured or not. I don't recall.  
11 But those type of analyses would have  
12 been fairly easy to do, in a manner  
13 similar to the types that we did for  
14 Duragesic.

15 Q. But they haven't been done  
16 by Janssen?

17 A. Well, I don't -- I don't  
18 know. My -- my testimony was that I  
19 don't recall seeing it. I don't know  
20 that they were not done.

21 As part of the usual  
22 pharmacovigilance-type work, we would  
23 have looked at the number of patients  
24 where the reports of addiction were given

1 to the company. So those type of data  
2 were being looked at regularly as part of  
3 the adverse events that we received from  
4 healthcare providers or from patients.

5 Looking at mentions of addiction,  
6 mentions of abuse and other types of  
7 adverse events.

8 Q. And you're also collecting  
9 it from the -- I don't recall the  
10 acronym, but the methadone clinics, that  
11 data?

12 A. Yes.

13 Q. You -- you would agree with  
14 me that adverse event data, MedWatch  
15 data, is typically underreported,  
16 correct?

17 A. I'm not following your  
18 question. First we were talking about  
19 the AATOD data which would have been a  
20 survey data. And then you asked me  
21 another part of the question about  
22 adverse event reporting. So I apologize,  
23 I'm not following you.

24 Q. The -- the -- what do you

1 call it, the AATOD data?

2 A. Yes.

3 Q. That is tracking individuals  
4 who are in methadone clinics, correct?

5 A. Yes.

6 Q. So those are individuals  
7 that have -- that are in a clinic for an  
8 actual addiction, correct?

9 A. Yes. Those are  
10 de-identified data on patients presenting  
11 to a clinic for methadone maintenance.

12 Q. And then adverse event data  
13 that you're discussing that goes to the  
14 FDA, that's -- that comes from all sorts  
15 of places, correct?

16 A. So the adverse event data  
17 that we pull to the FDA, we talked about  
18 that, it could come from MedWatch forms,  
19 it could come from healthcare providers.  
20 It could come from consumers that use our  
21 products. It could come from a wide  
22 range of individuals.

23 Q. And would you agree with me  
24 that there are published studies that

1 talk about the underreporting of adverse  
2 events to MedWatch and others collected  
3 by the FDA?

4 A. Yes.

5 Q. But you believe using the  
6 AATOD and MedWatch data, that is -- that  
7 is satisfactory to determine the rate of  
8 iatrogenic addiction in patients  
9 prescribed opioids for chronic pain?

10 A. No. I think the AATOD data  
11 was again, individuals coming in for  
12 methadone maintenance who may have been  
13 on a variety of medications. So they  
14 may -- these people are individuals who  
15 are abusing medications. So they may  
16 have been on combination therapy. They  
17 may have been on benzodiazapines or other  
18 drugs as well.

19 The iatrogenic addiction  
20 data that I had referred to came from  
21 information coming into our  
22 pharmacovigilance, coming into the  
23 company through the passive surveillance  
24 program.

1           Q.     Do you believe there's any  
2     current need for a study to determine the  
3     rate of iatrogenic addiction in chronic  
4     pain patients taking opioids?

5           A.     I think a study like that  
6     would be a difficult study to do. I  
7     think we'd need to understand what  
8     patients we would be looking at, what  
9     drugs we would be looking at.

10                  FDA in its -- the REMS  
11     requirements, looking at the types of  
12     drugs, the types of studies that they  
13     were interested. My understanding is  
14     they were looking at entities like  
15     hyperalgesia and some other things as  
16     well. So a study on iatrogenic addiction  
17     certainly could be one that might be of  
18     interest to the FDA. So I would be  
19     interested in knowing if such a study was  
20     required by FDA for the REMS  
21     participants. And I don't know whether  
22     it was or was not.

23           Q.     The experts at the Ad Board  
24     believed there was a need for a study to

1 determine the rate of iatrogenic  
2 addiction, correct?

3 A. Yes. That was in 2003. The  
4 current requirements to set up with the  
5 REMS, again as we talked about, where the  
6 FDA had decided on what studies they  
7 would need to gain more information about  
8 opioid analgesics, so I would defer to  
9 the FDA requests for the type of data  
10 that they feel would be pressing to get  
11 more information.

12 There's certainly a concern  
13 about addiction as you voiced today and  
14 what would be the best types of studies.  
15 They would be in a position to guide the  
16 industry as a whole to begin to look at  
17 those types of studies potentially.

18 Q. While you were at Janssen,  
19 would it be fair to say then that you did  
20 not believe, at least after the Ad Board  
21 in 2003, that there wasn't a need -- that  
22 there was a need for Janssen to perform  
23 any sort of a study to determine the rate  
24 of iatrogenic addiction in pain patients

1     prescribed opioids?

2             A.     So I think we had ongoing  
3     analysis of our patients treated with our  
4     products, to understand rates of  
5     addiction. And I think they did a good  
6     job and continued to do a good job  
7     certainly up until when I had -- when I  
8     was knowledgeable before I left, that we  
9     monitored for abuse and addiction for our  
10    patients.

11            Q.     So you don't believe you  
12    needed it?

13            A.     I think -- and I think --  
14    and if I'm understanding your question  
15    correctly, you asked do we -- do I think  
16    there's a need for studies looking at  
17    iatrogenic addiction. Those may be  
18    industry spun -- studies for the  
19    industry. I think our company did a good  
20    job using the accepted methodologies  
21    looking at iatrogenic addiction at the  
22    time.

23            Q.     So you don't think it was  
24    necessary for Janssen to do that sort of



1 a study?

2 A. I think we had those data  
3 covered through the current  
4 methodologies.

5 Q. So you knew the answer?

6 A. I'm sorry?

7 Q. So you knew the answer?

8 A. We believe we had the answer  
9 for it.

10 Q. You were -- one of the  
11 exhibits marked early was Exhibit 13,  
12 which was your study, observational study  
13 of health-related quality of life and  
14 pain outcomes in chronic low back pain  
15 patients treated with fentanyl  
16 transdermal system.

17 A. Excuse me, yes.

18 Q. 13.

19 A. Yes. Let me find it. Okay.

20 Q. Is there a reason why you  
21 did not include an addiction endpoint in  
22 this study?

23 A. There was not an addiction  
24 endpoint that we would have had in the

1 clinical trial. So consequence --  
2 consequently we wouldn't have had the  
3 data we would be able to publish in this  
4 article.

5 Q. So it was not asked during  
6 the clinical study?

7 A. To the best of my knowledge,  
8 it was not.

9 Q. Do you know for sure?

10 A. I am fairly certain that we  
11 did not ask the question.

12 Q. Do you know if there were  
13 any questions with respect to dependence  
14 or abuse?

15 A. That would have been  
16 information that may have been identified  
17 in conversations between the  
18 investigators and their patients in the  
19 clinical trials. Which would -- that  
20 would have been part of the ongoing care  
21 that investigators would have given for  
22 their patients in clinical studies.

23 Q. Do you know what the  
24 preselection criteria was for the

1 individuals in the clinical study that  
2 was used for your observational study?

3 A. These -- these refer back to  
4 the two clinical trials. I would need to  
5 look at the protocols and refer back to  
6 be able to answer that question.

7 Q. If it had, if -- if those --  
8 if those clinical studies had described  
9 some of that data with respect to either  
10 dependence or abuse or addiction, would  
11 you have included it in this article?

12 A. Yes. It would have been  
13 part of the adverse events. It may not  
14 have been in this article, but it would  
15 have been in part of the publications  
16 we -- that we were interested in putting  
17 out for the -- for this particular trial.  
18 Because it would have been important  
19 adverse events that we would have wanted  
20 to report on.

21 Q. You spoke about Exhibit 16,  
22 which is the cumulative review of  
23 iatrogenic addiction associated with the  
24 use of the transdermal Duragesic patch.

1 We spoke about that a little bit earlier.

2 I just want to ask you one question about

3 it. You -- you talked about the 103

4 events in a billion 611 patient hours?

5 A. I believe it was patient

6 days.

7 Q. Patient days. That's not --

8 so --

9 A. Days on drug therapy.

10 Q. Do you know how many

11 patients? It's not 103 events with a

12 denominator of a billion 611, correct?

13 A. Well, the patient days would

14 be the number of exposures that we were

15 talking about. And patient days is a

16 typical methodology that FDA has to

17 understand patient exposures for a

18 specific medication.

19 As I had provided in my

20 testimony earlier today, I had indicated

21 that the 103 number is likely a low

22 number. Because we know there's

23 underreporting, and you had made that

24 point as well.

1                   But even with the  
2     denominator being so large, that even if  
3     the numerator were double or triple in  
4     size, the number would still be quite  
5     small and that the -- the statement of  
6     events being rare, I think is still a  
7     reasonable statement, even if we were off  
8     by a factor of five, where the numerator  
9     would be much larger, again the  
10    denominator being so large that the risk  
11    of iatrogenic addiction would still be,  
12    in my opinion, quite low. And I would  
13    still agree with the statement of rare.

14                Q.     Okay. I didn't ask you  
15    that, but thank you.

16                A.     No, you didn't.

17                Q.     When we are talking about  
18    patient days, we are talking about every  
19    day that a patient takes the medication,  
20    correct?

21                A.     A day that the patient's on  
22    the medication.

23                Q.     Right. And the 103 events  
24    are related to a diagnosis or an event or

1 report of an adverse event on one day?

2 A. I'd have to go look and see  
3 how that was defined. Sometime --  
4 whether this was a single event or  
5 multiple events and how this would be  
6 collected.

7 Q. Because the number of  
8 patient days does not correspond to the  
9 number of patients that are on the drug,  
10 correct?

11 A. It's -- that's right. We  
12 have a person who might be on the drug  
13 for a number of days, and those would be  
14 days of exposure, or a likelihood that  
15 they would have been able to be in a  
16 position where they would have had the  
17 adverse event.

18 Q. So the denominator -- if  
19 you're talking about the number of  
20 patients who had an adverse event, the  
21 denominator would be the number of  
22 patients, correct?

23 A. Well, the number of times  
24 that people would have had an opportunity

1 to have the exposure, that's why this is  
2 recorded as patient days. Beyond the  
3 drug, basically have an opportunity to  
4 have the event. So it's not only the  
5 total number of patients, but it's the  
6 individuals that are actually on the  
7 medication at the time.

8 So as I had already just  
9 stated and I apologize for being  
10 redundant, patient days is one of the  
11 ways we look at this.

12 Q. Correct. But --

13 A. And again, this was a  
14 request that FDA had to us in terms of  
15 how we would look at the data.

16 Q. Do you know how many  
17 patients had 103 events?

18 A. I don't know.

19 Q. Or is that knowable?

20 A. I don't know if it's  
21 knowable. I do not know it.

22 Q. That's not something you've  
23 looked at?

24 A. No. This was an analysis

1 done by other individuals. And so I  
2 don't know.

3 Q. You were shown Exhibit 19,  
4 which was the Duragesic label. And my  
5 question is just that the term  
6 "pseudoaddiction" does not appear in this  
7 label, correct?

8 A. That is correct.

9 Q. The FDA would not allow you  
10 to use that term, correct?

11 MR. LIFLAND: Object to the  
12 form of the question.

13 THE WITNESS: That term was  
14 not included in the product label.

15 BY MS. CONROY:

16 Q. And that's because the FDA  
17 would not approve the product label with  
18 that term in it, correct?

19 A. We had --

20 MR. LIFLAND: Object to the  
21 form of the question.

22 THE WITNESS: We had been in  
23 communication with the FDA about  
24 the use of the label --



1           pseudoaddiction in the label. And  
2           after discussion, FDA had not  
3           included it. So I don't know  
4           whether they allowed or didn't  
5           allow it. But the fact is, it's  
6           not in the label.

7   BY MS. CONROY:

8           Q.     Okay. Would you agree with  
9           me that Janssen at least at some point in  
10          the negotiation wanted the term  
11          pseudoaddiction in the label?

12          A.     No. I think the idea was we  
13          asked whether pseudoaddiction in the  
14          label would be appropriate because the  
15          label had been modified to include  
16          individuals engaged in drug-seeking  
17          behavior. And our position was that, as  
18          we've indicated earlier, and -- was that  
19          there are people who may have legitimate  
20          reasons for needing the medications.

21                  FDA agreed with the premise  
22          that there may be individuals who  
23          manifest drug-seeking behavior who are  
24          not necessarily doing that with ill

1 intent.

2 And I use that as evidence  
3 because in the product label, as we  
4 talked about, that type of behavior is  
5 described.

6 Q. Correct. But you were not  
7 allowed to use the word "pseudoaddiction"  
8 in the label?

9 A. FDA -- in our communications  
10 back and forth, pseudoaddiction was not  
11 something that was used in the label.

12 Q. Would you agree with me that  
13 you can become addicted to a chronic  
14 opioid pain medication even if you don't  
15 crush it or shoot it up or otherwise  
16 alter the pill or the patch? You can  
17 still become addicted?

18 A. Yes.

19 Q. I think you referenced --  
20 well, let me -- let me mark as Exhibit 23  
21 a document that I think you were  
22 referring to. Tell me if not.

23 (Document marked for  
24 identification as Exhibit

1 Janssen-Vorsanger-23.)

2 BY MS. CONROY:

3 Q. Doctor, this is a document  
4 concerning a pain coalition. Are you  
5 familiar with what that was?

6 A. I am.

7 Q. And what was the pain  
8 coalition? Or let me identify the  
9 document first. So this is Exhibit 23.  
10 JAN-MS-02057424 through 435.

11 What was the pain coalition?

12 A. We were interested in  
13 understanding the challenges that people  
14 who took care of patients with pain were  
15 facing at the time.

16 So we put together a  
17 committee, a pain coalition comprised of  
18 a number of different types of people.  
19 We had people with expertise in pain  
20 management. We had -- I believe we had  
21 nurses who attended, who would take care  
22 of patients or who provide analgesia for  
23 patients. I had -- there were two people  
24 on the pain coalition who actually had

1 chronic painful conditions. So a variety  
2 of different people got together to share  
3 their experiences with taking pain  
4 medications or with their diseases of  
5 pain.

6 Q. If you take a look at --  
7 there aren't any -- in the very first few  
8 pages there's a PowerPoint attached to  
9 this. And there are some coalition  
10 members that are listed here.

11 A. Yeah. I'm still getting  
12 there. Say -- you wanted -- PowerPoint,  
13 okay.

14 Q. Yeah. It says, "Imagine the  
15 Possibilities Pain Coalition."

16 A. Yes.

17 Q. "Next Step Slides." And  
18 then there are some individuals that are  
19 referenced here. You are mentioned, some  
20 other Janssen individuals.

21 A. Under coalition members  
22 you're referring?

23 Q. Yes.

24 A. Okay. Yes.

1           Q.     And where it says at the  
2     bottom, "Payer sector representation  
3     forthcoming."

4           A.     Yes.

5           Q.     "Geisinger, Medco and  
6     B/Horizon." Do you know who they are?

7           A.     I'm not seeing --

8           Q.     It's the one that has Gary  
9     Baker on the top?

10          A.     Yes. I saw patient (sic)  
11     sector representation following. But I  
12     didn't see a reference for the other  
13     entities that you just said. I don't see  
14     it on the slide.

15          Q.     Just let me see what  
16     you're -- keep going. Look on the slide  
17     earlier than that.

18          A.     Oh, it's on this one.

19          Q.     Yeah?

20          A.     I'm sorry. Okay. So I  
21     thought it was the members. So the  
22     coalition follow-up -- members follow-up.

23          Q.     Okay.

24          A.     Okay, yes.

1           Q.     Do you know who Geisinger  
2     is?

3           A.     I do.

4           Q.     Who is that?

5           A.     It's a group that is  
6     involved in healthcare. And we -- as I  
7     mentioned we wanted to have different --  
8     representation from different people who  
9     care for patients with pain. So  
10    individual in the Geisinger group who may  
11    have had pain, and also we were  
12    interested in some of the other people  
13    who were involved in providing pain med  
14    for people with pain -- use of their pain  
15    medications.

16          Q.     Was Geisinger connected or  
17    affiliated with Johnson & Johnson or  
18    Janssen?

19          A.     I don't know. I don't know  
20    what their affiliation or relationship  
21    was. Our intent on having someone from  
22    Geisinger is as I just explained.

23          Q.     Medco, what's that?

24          A.     I don't remember.

1 Q. Do you remember what  
2 B/Horizon was?

3 A. I don't.

4 Q. If you flip through the  
5 document. And now, we'll start to see,  
6 after you get through the first few  
7 pages. In the lower right-hand side in  
8 the black box, there's a little number.

9 A. Yes.

10 Q. I think there's a three on  
11 the one that you're looking at right now?

12 A. I do.

13 Q. Turn the page to Page 4.

14 A. Okay.

15 MR. LIFLAND: Sorry. Give  
16 me a second.

17 MS. CONROY: Keep going.  
18 No, way too far. Keep going back.

19 MR. LIFLAND: I don't see  
20 any numbers. I see 12.

21 MS. CONROY: Go to 4.

22 MR. LIFLAND: Okay, thank  
23 you.

24 BY MS. CONROY:

1           Q.     Do you see where it says,  
2     "Coalition's first goals"?

3           A.     Yes.

4           Q.     And were you the author of  
5     that? Were you the one that determined  
6     the goal?

7           A.     These, I believe, would have  
8     been goals that would have been decided  
9     upon by the participants in the  
10    coalition.

11          Q.     So it would have been the  
12    group that we saw above, would have come  
13    up with this coalition's first goals?

14          A.     It would have been the  
15    people who were defined as coalition  
16    members that we have listed at the  
17    bottom.

18          Q.     If you look a little bit  
19    above that, the top areas to focus on,  
20    "Targeted, effective communication to  
21    healthcare professionals." And that  
22    would be communication to medical  
23    schools, existing professionals and  
24    specialists in pain.



1 Do you see that?

2 A. Yes.

3 Q. Anything different about  
4 that, or is that typically an audience  
5 for communication on Janssen products?

6 A. This is not unusual. This  
7 would have been the recommendations of  
8 the members of the pain coalition.

9 Q. What about where, in the  
10 middle, it says, "Inform public attitude,  
11 social media, trusted websites, hit media  
12 that hit bigger footprints with younger  
13 audiences. Focus on living with pain."

14 Is there a reason that were  
15 you looking to a younger audience?

16 A. I don't recall the reason at  
17 the moment. But, again, this would have  
18 been information that would have been --  
19 this would have -- this would have been  
20 guidance from the various members.

21 Q. And you were one of the  
22 members?

23 A. I was along with the other  
24 people whom are listed as coalition

1 members. Yes.

2 Q. Okay. If you can turn to  
3 Page 19. You see where it says, "Top  
4 issues in pain management"?

5 A. I'm sorry. I'm still  
6 getting there.

7 Q. Sorry.

8 A. Yes.

9 Q. There are three teams listed  
10 here?

11 A. That's correct.

12 Q. Do you know which team you  
13 were on?

14 A. I don't recall.

15 Q. Okay. Under Team 3 it says,  
16 "Payer systems, add a member from here to  
17 this team, and the impact of healthcare  
18 reform."

19 Do you know if a member was  
20 added at any point?

21 A. My recollection is that  
22 there was somebody who ultimately was  
23 added. But I don't know who that person  
24 was.

1 Q. Okay. And if you look under  
2 Team 1?

3 A. Yes.

4 Q. There's a prevention  
5 section. Is that the prevention of pain?

6 A. Yes.

7 Q. And it says, "Potentially  
8 work with professional athletes,  
9 targeting kids to approach pain  
10 management more proactively."

11 Do you see that?

12 A. Yes.

13 Q. Do you know which of the  
14 members was working on that?

15 A. No, because we didn't have a  
16 list of who it would be. So we  
17 identified top issues in pain management  
18 from the coalition, and then listed out  
19 some of the objectives for each of the  
20 teams. And people could sign up for what  
21 they have. But I don't know who was on  
22 each of the teams at this point. I don't  
23 remember.

24 Q. Do you know if there were

1 meeting minutes or anything like that  
2 with respect to this pain coalition?

3 A. I don't recall.

4 Q. Was it -- was the pain  
5 coalition something that was within the  
6 medical affairs department?

7 A. Not specifically. I was  
8 involved in it, helped organize it.  
9 Robyn Kohn who was my co-chair was  
10 someone who was in the advocacy group.  
11 So we had this type of involvement, but  
12 there were people -- it was -- there were  
13 other people within the company that were  
14 involved as well.

15 But I think this was an  
16 activity run mostly through medical  
17 affairs.

18 Q. Okay. The advocacy group,  
19 is that a marketing group?

20 A. The advocacy group is a  
21 group that provides information I believe  
22 to groups as requested for that type of  
23 information. But I don't have their  
24 charter. And I don't remember what they

1 are doing. So I want to be careful not  
2 to answer that. Because I'm not sure.

3 Q. Okay.

4 A. Yeah.

5 Q. But you do recall that it  
6 was called the advocacy group?

7 A. Yes, I do.

8 Q. So they would be somewhere  
9 on an organizational chart?

10 A. Presumably.

11 Q. Okay. If you can turn to  
12 Page 29. I'm sorry, 28. You're free  
13 to -- if you need to look at any of the  
14 earlier slides, that's fine. But there's  
15 the public -- Slide 28 is the public  
16 health outreach. And we are talking here  
17 about, this is a callout of the section  
18 that we saw in the previous slide  
19 concerning the prevention of pain.

20 Do you see that?

21 A. Yes.

22 Q. And the -- it says, "Focus  
23 on athletes, young, old, professional.  
24 Work with trainers, young, old

1 professional. And work with groups like  
2 the NFL."

3 That's the National Football  
4 League, correct?

5 A. Yes.

6 Q. -- "to destigmatize pain  
7 treatment and better understand abuse."

8 Do you see that?

9 A. Yes.

10 Q. Do you know if there was a  
11 focus on athletes for pain management?

12 A. I don't recall.

13 Q. Who would know that?

14 A. I don't know. I don't  
15 know -- I don't know if there are  
16 minutes, et cetera. I think -- I don't  
17 know.

18 Q. Okay. Do you know if there  
19 was any work done with the NFL to  
20 destigmatize pain treatment?

21 A. No, I think this was  
22 aspirational.

23 Q. I don't know how I'm going  
24 to get you here. If you go to Page 37,

1 and then there's a native -- okay, you  
2 found it. That logo. Turn the page, go  
3 to the next one. And it says Meeting  
4 Number 2, October 12th of 2011.

5 A. Excuse me.

6 Q. So this appears to be a  
7 second meeting of the group. Do you see  
8 that?

9 A. Yes.

10 Q. And is it your memory that  
11 there was more than one meeting of the  
12 group?

13 A. I remember a second meeting  
14 which comes to mind now as I'm looking at  
15 it.

16 Q. Okay. And it says, "Welcome  
17 new members and expanded communities."  
18 Do you see that, Bob, Scott, Pam and  
19 Phyllis?

20 A. Yes.

21 Q. Do you know who they are, do  
22 you remember?

23 A. I'm not certain.

24 Q. And at the bottom of that

1 page it says, "Explored private and  
2 public funding sources." Do you have any  
3 recollection that that was done?

4 A. I don't know. I don't have  
5 a recollection of whether that was done.

6 Q. If you turn the page, and  
7 I'm looking for media outreach  
8 initiatives which is maybe two pages on.  
9 Reaching out to youth. Reach early,  
10 elementary school level, via respected  
11 channels, for example coaches. Deliver a  
12 practical message. Pain is your body  
13 telling you something important.

14 Do you see that?

15 A. On the next page, I'm sorry.

16 Q. Do you see it?

17 A. Yes.

18 Q. Do you agree with that, that  
19 pain is your body telling you something  
20 important?

21 A. Yes.

22 Q. If you go a couple of more  
23 pages to where you see at the top, "Pain  
24 policy, advocacy sub-team platform," at



1 the top.

2 A. Yes.

3 Q. And the bullet point says,  
4 "Chronic pain is the number one public  
5 health problem."

6 Do you see that?

7 A. Yes.

8 Q. Do you agree with that?

9 A. I don't know if it's the  
10 number one public health problem. It's  
11 certainly an important public health  
12 problem.

13 Q. Okay. It says, "The  
14 priority area of focus. An epidemic of  
15 pain versus an epidemic of addiction."

16 Do you see that?

17 A. Yes.

18 Q. Do you agree that there is  
19 an epidemic of addiction in the United  
20 States?

21 A. I think there's an epidemic  
22 of abuse. And I -- there may be people  
23 who are addicted, I'm not sure. I'd have  
24 to think a little bit about that.

1 Q. Okay. What about an  
2 epidemic of pain?

3 A. I think there was -- in  
4 2011, I think there was a sense that pain  
5 was undertreated and that individuals  
6 had -- who deserved legitimate treatment  
7 for their pain was something that would  
8 need to be addressed.

9 Q. Do you think it was an  
10 epidemic?

11 A. I'm not sure exactly whether  
12 it -- whether it was a criteria that  
13 would fit for epidemic or not. And  
14 again, some of this may have been  
15 aspirational or perceptions. I don't  
16 have the -- I don't have the supporting  
17 framework to understand what -- what we  
18 were meaning by these statements.

19 Q. Okay. If you keep going a  
20 few pages, there's a third meeting in  
21 February of 2012. There's a meeting  
22 summary. Do you see that?

23 A. I see February 2012 meeting  
24 summary.

1 Q. Okay.

2 A. Yeah.

3 Q. And is it your memory that  
4 you would have still been a part of this  
5 pain coalition as of the third meeting in  
6 February of 2012?

7 A. Quite possibly. I can't --  
8 I don't recall if I was at the entire  
9 meeting, but I was involved with the pain  
10 coalition.

11 Q. Okay. And so you would  
12 have -- you would have received -- the  
13 slides either would have been available  
14 and watching them when they were shown or  
15 you would have received copies of them?

16 A. We would have had some --  
17 some information around this meeting.

18 Q. If you keep turning the  
19 pages, you'll get to the fourth meeting.

20 A. You had asked a question  
21 earlier, counselor, about epidemics,  
22 et cetera, and I think what's important,  
23 we focus -- when we talk about this  
24 relieving pain, the Institute of Medicine

1 report. Because that was a blueprint for  
2 pain management in the U.S., and a number  
3 of the issues related to pain prevention  
4 as a public health issue. And  
5 communicating with public and policy  
6 members, state legislators, some of those  
7 were things that came out from the IOM  
8 report. So I want to make sure that it's  
9 clear for the record that this types of  
10 thinks -- thinking was based on a  
11 government-generated document.

12 Q. When was the Institute of  
13 Medicine report issued?

14 A. I'd have to look and see  
15 when that is. But it -- the title is --  
16 it's easily findable from the Institute  
17 of Medicine report. And I think it was a  
18 blueprint for the -- I'm paraphrasing the  
19 title.

20 But that -- that addresses a  
21 number of the thinking for the committee  
22 members around what we had hoped to  
23 accomplish.

24 Q. Do you know if that

1 Institute of Medicine report was issued  
2 prior to the pain coalition getting  
3 together?

4 A. I don't remember the timing.

5 Q. Okay. If you keep --

6 A. But I do remember that one  
7 of the members of the pain coalition was,  
8 I believe, a participant in the IOM  
9 report. And would have been able to  
10 inform us certainly about the report and  
11 its findings. And that was one of the  
12 reasons why we had this cross-functional  
13 team of individuals participating in it.

14 Q. Do you remember -- do you  
15 remember that person's name?

16 A. I believe it was Dr. Richard  
17 Payne. And if you search the blueprints  
18 for Payne -- I don't know what the title  
19 is. It's the IOM report. I believe that  
20 Dr. Payne was one of the participants and  
21 a contributor.

22 Q. And was he -- was he paid  
23 for his time on the pain coalition, do  
24 you remember?

1           A.     I don't recall.

2           Q.     Do you know if anyone was,  
3     who was not a Janssen employee?

4           A.     I don't recall the specifics  
5     around the funding. The company was  
6     interested in not having it come  
7     specifically from Janssen, which is why  
8     you had called out public or private  
9     funding. And it was -- the intent was to  
10    not have it necessarily come from a  
11    pharmaceutical company, but to have  
12    independent funding. That was something  
13    that was aspirational. And I believe we  
14    thought that it would be something that  
15    might take time to develop. So Janssen  
16    was involved initially, but again with  
17    the idea of handing it off to a more --  
18    to a different organization that would be  
19    funding it.

20          Q.     Do you know if that ever  
21    happened?

22          A.     I don't know if the  
23    coalition was around that long to enable  
24    it to happen. I don't know.

1           Q.     Okay. You can put that  
2     document away.

3                     Doctor, at the start of the  
4     direct examination by Mr. Lifland today,  
5     you said that you did not have primary --  
6     primary responsibility for marketing or  
7     for sales or for compliance. Do you  
8     recall that testimony?

9           A.     I do.

10          Q.     You were involved, however,  
11     with marketing, sales and compliance. So  
12     what you did touched on those areas,  
13     correct?

14                     MR. LIFLAND: Object to the  
15     form of the question.

16                     THE WITNESS: Some of my  
17     activities at the company were in  
18     a position that I would have  
19     interacted with people on those --  
20     you know, but again as you stated  
21     those were not my primary  
22     responsibilities.

23     BY MS. CONROY:

24          Q.     Correct. Your primary

1 responsibility was medical affairs.

2 A. Yes, that's correct.

3 Q. You did sit on the  
4 promotional review committee, correct?

5 A. Yes.

6 Q. And what years did you sit  
7 on that?

8 A. I don't have -- I don't have  
9 the data, the time I was on it.

10 Q. Did you tell me this? I  
11 don't remember. Was it a couple of  
12 years?

13 A. Yes. It was -- I don't  
14 remember how long it was. It was years.  
15 But I don't remember how many years. And  
16 I don't remember when I started on it.  
17 And I don't remember when I finished  
18 serving on it.

19 Q. You had testified in  
20 response to some questions by Mr. Lifland  
21 that abusers are looking for a, quote,  
22 quick high. Do you remember that?

23 A. I do.

24 Q. What studies support the



1 fact that an abuser is looking for a  
2 quick high as opposed to a higher dose  
3 for pain -- for a pain problem or to  
4 avoid withdrawal syndromes?

5 A. I don't have specific  
6 studies that I can give you offhand  
7 today. I think when we talked to our  
8 experts and individuals who are  
9 knowledgeable, the general teaching and  
10 what people understand, is that, as I  
11 testified earlier, the faster the  
12 medication can reach the central nervous  
13 system, the more potentially desirable it  
14 would be for people who abuse these  
15 products.

16 Q. But do you know if they feel  
17 a high or if they're feeling withdrawal?

18 A. I don't understand your  
19 question. I'm sorry.

20 Q. Looking for a faster  
21 medication to hit the central nervous  
22 system, correct?

23 A. Yes.

24 Q. That's what we're

1 discussing?

2 A. Yes.

3 Q. Do you know if the desire  
4 for that faster medication to hit the  
5 central nervous system is to experience a  
6 high or to avoid the lows of withdrawal?

7 A. It may be both.

8 Q. Do you know of any evidence  
9 that chronic pain patients taking opioid  
10 medication are experiencing quick highs?

11 A. I do not. You mean using  
12 the medications as prescribed to treat  
13 their chronic pain?

14 Q. Yes.

15 A. I'm not aware of any study  
16 like this.

17 Q. Are you aware of any  
18 evidence of chronic pain medications  
19 taking opioids who misuse their  
20 products -- misuse the products taking it  
21 for a quick high?

22 A. Not that I'm aware of.  
23 There may be. No. Not that I'm aware  
24 of.

1           Q.     Do you know if there are  
2     any -- any studies looking at chronic  
3     pain patients taking opioid medications  
4     who misuse those opioid medications that  
5     are looking to escape withdrawal --  
6     withdrawal symptoms?

7           A.     So that would be a study  
8     where an endpoint would have been asking  
9     the people why they were taking the  
10    medications. And I'm not aware of that  
11    type of study where those type of  
12    endpoints would have been predefined in  
13    the study to be able to answer that  
14    question.

15          Q.     So you're not aware of a  
16    study with predefined endpoints of either  
17    a quick high or avoidance of withdrawal?

18          A.     Where participants would  
19    have been asked those questions, no. For  
20    both of those two questions, no.

21          Q.     You mentioned Dr. Cynthia  
22    McCormick sat on the external advisory  
23    board. Do you recall that testimony?

24          A.     Yes.

1           Q.     And when she was on the  
2     external advisory board at Janssen, was  
3     she still at the FDA?

4           A.     No, she was not.

5           Q.     And was she paid for her  
6     time on the external advisory board?

7           A.     I believe she was. She was  
8     a consultant to the company.

9           Q.     Okay. Do you know if there  
10    was a separate payment for the external  
11    advisory board or would that have been  
12    covered in a consultancy agreement?

13          A.     I don't remember the  
14    specifics around how it was done.

15          Q.     Do you know if she had to  
16    get permission from the FDA to enter into  
17    a consulting agreement with Johnson &  
18    Johnson, Janssen?

19          A.     I don't know the answer to  
20    that question.

21          Q.     And would you remind me. Do  
22    you have a memory of the external  
23    advisory board actually meeting?

24          A.     Yeah. The external review

1 committee met quarterly in Philadelphia,  
2 which I had testified to.

3 Q. You did tell me that. Thank  
4 you.

5 MS. CONROY: Let me -- let's  
6 take a quick break. I want to  
7 find that reference in the Ad  
8 Board for you.

9 THE VIDEOGRAPHER: The time  
10 is 3:52 p.m. Going off the  
11 record.

12 (Short break.)

13 THE VIDEOGRAPHER: The time  
14 is 4:03 p.m. We are back on the  
15 record.

16 BY MS. CONROY:

17 Q. Doctor, during the break I  
18 wanted to see if I could find in the Ad  
19 Board summary the reference to the  
20 discussion about selection of patients  
21 for opioid treatment.

22 And if you could turn to  
23 Page 39, please, of Exhibit 9. And if  
24 we -- are you there? At the bottom of

1 the page it's talking about, this is the  
2 section that was discussing various  
3 epidemiological studies that could be  
4 conducted. And if you look at the bottom  
5 of Page 39, it says how to define -- how  
6 to define the population to follow up in  
7 an epidemiological study. And then, as  
8 you continue to go through this, and  
9 you're free to look, if you want to, but  
10 on Page 40, it says you could use  
11 screens, screen a large number of people,  
12 if we had a good screening instrument for  
13 vulnerability. Do you see that?

14 A. I don't see it yet.

15 Q. Okay. Right before -- at  
16 the bottom it says, "An ethical  
17 issue/dilemma," on 40. And then right  
18 above it talks about a good screening --

19 A. Yeah. Let me look at the  
20 answer above that if I might.

21 Q. Sure.

22 A. Okay. I see the statement  
23 about, "So maybe then you could use  
24 screens for example," that's the one

1     you're referring to?

2             Q.     Well, I just wanted to  
3     orient you in -- into the section and  
4     what we're discussing is how you would  
5     either identify high risk individuals,  
6     individuals who are at risk for addiction  
7     if they are given opioids for chronic  
8     pain, or to assist in the preselection of  
9     patients for opioid treatment. You -- so  
10    I was just trying to orient you.

11            A.     I see.

12            Q.     Okay. Do you recall  
13    discussions about how to determine or how  
14    to screen for the proper or appropriate  
15    patients for opioid treatment?

16            A.     Do you mean by recall,  
17    recall from the conversation in the  
18    advisory board?

19            Q.     Yes.

20            A.     Yes, I have some  
21    recollection of this discussion.

22            Q.     Okay. Then if you turn to  
23    Page 42. At the bottom it says B-4 H,  
24    how to identify high risk people. Do you

1 see that?

2 A. Yes.

3 Q. And it says, "Most of the  
4 studies show that people that do become  
5 dependent on prescription opiates had a  
6 childhood or an adolescent onset of some  
7 other kind of substance abuse. They are  
8 marijuana abusers, et cetera, not just  
9 users."

10 Do you see that?

11 A. Yes.

12 Q. And do you have an  
13 understanding of the extent to which  
14 preselection would include individuals  
15 who use marijuana?

16 A. I would need to understand  
17 what they mean by this statement. And  
18 it -- so there's not enough information  
19 for me to talk about the distinction  
20 between -- I understand the terms but I  
21 don't understand the context. So  
22 substance abuser, I understand, versus a  
23 casual user. In this case just users.

24 Q. Okay. Have you ever looked



1     into the issue of whether or not an  
2     individual who suffers from depression  
3     could potentially be at higher risk for  
4     addiction if prescribed opioids for pain?

5             A.     I'm aware of the fact that  
6     people who may have psychiatric disorders  
7     may be at higher risk for issues and  
8     problems with opioid therapy.

9             Q.     And have you been -- has  
10    that been fairly well known since your  
11    time at Janssen, or is that something  
12    more recent?

13            A.     It's something that's been  
14    known for sometime. I don't know how  
15    long it would be, to precisely answer  
16    your question.

17            Q.     Okay. You can put that  
18    away.

19                    Earlier today during  
20    questioning by Mr. Lifland, you talked  
21    about publications. And you said there  
22    was a procedure in place that studies  
23    that were undertaken would be published.  
24    Do you recall that?

1           A.     As part of their -- the --  
2     the company had a policy, I don't know if  
3     it was a procedure. The company had a  
4     policy that studies that were undertaken  
5     would be published.

6           Q.     And I just want to  
7     understand that a little bit more.

8                     Would they be -- would there  
9     be an attempt to have them published in a  
10    peer-reviewed publication first, or are  
11    we talking about published online or --  
12    what -- what do you mean by published?

13          A.     So the intent would be to  
14    have the data presented in a  
15    peer-reviewed article -- a peer-reviewed  
16    journal, or presented at a -- at a  
17    professional meeting where the  
18    information would be peer reviewed.

19                    But just to clarify, make  
20    sure that I understand your statement,  
21    the online journals are -- are frequently  
22    peer reviewed.

23          Q.     I guess my question more  
24    was, is it true that every study

1     undertaken at Janssen would ultimately be  
2     published somewhere?

3             A.     This would be an attempt to  
4     try and publish it someplace. The study  
5     may not always be accepted, but it would  
6     be submitted for some type of  
7     publication, presentation in a meeting or  
8     the like.

9             Q.     And it would just --  
10    every -- every study would be published,  
11    it would just be a difference with  
12    respect to the level of peer review or  
13    whatever it might be, where that study  
14    might be accepted?

15            A.     I'm not understanding your  
16    question.

17            Q.     Well, what if -- what if a  
18    study is submitted to three different  
19    journals and it is not accepted? Would  
20    that study then be published in a poster,  
21    for example, at an American Pain  
22    Management conference or would there be  
23    some attempt to have it published  
24    somewhere?

1           A.     Yes.

2           Q.     Were there ever situations  
3     where it was impossible to get something  
4     published?

5           A.     With one of our studies --  
6     actually, for two of our studies the  
7     primary endpoint data, we submitted it to  
8     multiple journals to be published and  
9     they were rejected. We did present that  
10    in an abstract poster at a professional  
11    meeting. As I've just indicated, it is  
12    part of our responsibility to disseminate  
13    this type of information to the public.

14               And then additional  
15    information was published on some of the  
16    secondary endpoints, so for example the  
17    article that I presented, that we  
18    discussed today on quality of life.

19           Q.     Okay. And what were -- what  
20    were the topics. Did you say there were  
21    two of those that you're aware of?

22           A.     Yeah, I referenced those two  
23    studies. The study looking at patient  
24    preference compared to OxyContin and the

1 study comparing patient preference to  
2 Percocet, those two study.

3 Q. Patient preference with  
4 reference to -- I couldn't hear you.

5 A. There were two studies that  
6 we talk about. One was a patient  
7 preference comparing transdermal fentanyl  
8 to OxyContin, extended-release oxycodone,  
9 and a second study with a very similar  
10 design comparing the use of transdermal  
11 fentanyl to Percocet for patient  
12 preference.

13 Q. And both of those were  
14 presented via poster?

15 A. That's my recollection. I  
16 don't know if those are separate posters  
17 or one posters. I don't remember how it  
18 was. But it was disseminated through a  
19 poster or an abstract. That would have  
20 been submitted to a professional society.

21 (Document marked for  
22 identification as Exhibit  
23 Janssen-Vorsanger-24.)

24 BY MS. CONROY:

1           Q.     Let me show you what I've  
2     marked as Exhibit 24. Exhibit 24 is an  
3     e-mail with a manuscript attached dated  
4     February 21st, 2003. JAN-MS-02103693.

5                     Doctor, do you know if the  
6     manuscript that's attached -- you are an  
7     author and Dr. Nat Katz is an author as  
8     well as others. "Patient preference for  
9     treatment and difficulty with its  
10    interpretation: Result of two randomized  
11    controlled clinical trials."

12                    Do you know if this  
13    manuscript was published?

14           A.     I don't know.

15           Q.     Would it be your  
16    anticipation or would you have expected  
17    that it would be published somewhere?

18           A.     Yes. It looked like it was  
19    being prepared for publication.

20           Q.     Do you have any -- I could  
21    not find it, looking at it under this  
22    title. Do you recall whether or not this  
23    title changed?

24           A.     I don't know. I don't know

1     whether it would have been submitted and  
2     rejected, in which case, if you had done  
3     a search by the title, you would not have  
4     found it.

5             Q.     And so if it was -- if this  
6     was -- how would I find outfit was  
7     submitted and rejected? Where would that  
8     information be?

9             A.     That would have been part of  
10    the processes at Janssen where they would  
11    have identified where they submitted it  
12    and the outcome, what happened to it.

13            Q.     And what department would  
14    that be at Janssen?

15            A.     It might have been something  
16    that came out of medical affairs, but I  
17    don't know where that would be today.

18            Q.     Okay. Would medical affairs  
19    keep track of publications, what was --  
20    what was in print, what was approved for  
21    publication, that sort of thing?

22            A.     So publication strategy  
23    might have been done through medical  
24    affairs. How the company is currently

1 tracking publications, I can't comment.  
2 I simply don't know. And I don't know  
3 what type of processes would be in place  
4 to identify what was submitted and  
5 rejected at this time. At this -- you  
6 know, 15 years ago.

7 Q. Okay. Do you believe it was  
8 within your -- do you believe it was  
9 within medical affairs or someplace else  
10 at Janssen that would keep track of  
11 whether or not articles were published?

12 A. So medical affairs articles  
13 may have been tracked by personnel in  
14 medical affairs as part of the  
15 publication plan. But I don't know  
16 15 years ago, you know, how we would have  
17 been able to answer your question.

18 Again, it looked like it was  
19 formatted, or close to it, for  
20 submission. So it looked like there was  
21 an intent to submit to article at some  
22 point.

23 Q. You can put that one away.

24 (Document marked for



1                   identification as Exhibit

2                   Janssen-Vorsanger-25.)

3       BY MS. CONROY:

4                   Q.       We'll mark as Exhibit 25

5       JAN-MS-02077691 through 725 this is an

6       e-mail from you to Hany Rofael dated

7       June 2nd, 2014, with draft "Pain week

8       poster abstract: Withdrawal, dependance

9       and abuse."

10                               Is this an example of

11       something that made its way to a poster?

12       Do you know?

13                   A.       I don't know if this was

14       material that would have been presented

15       at a professional meeting. This looks

16       like it's set up here for a submission to

17       a journal. And it says Journal of Opioid

18       Management, TBD, high impact pain journal

19       with broad reach. So the intent was we

20       thought this would be information that

21       would be clinically valuable to a number

22       of different people. And once we have

23       the information, we would typically look

24       to decide what would be the best and most

1 appropriate journal. It looks like at  
2 this time we thought that this would be a  
3 journal that would be appropriate.

4 Q. Take a look at -- you have  
5 to go by the Bates number, 724. It's at  
6 the very end.

7 A. I'm sorry, I'm not seeing  
8 that.

9 Q. 724. It's the second to the  
10 last page of the document.

11 A. Oh, okay.

12 Q. And this is a -- you wrote  
13 this article, correct? Or you were one  
14 of the authors?

15 A. I was one of the authors.

16 Q. The very end of the article  
17 says, "Can a chronic pain patient become  
18 addicted to opioid drugs?"

19 Do you see that?

20 A. Yes.

21 Q. And in the middle of that --  
22 actually, the final sentence of the  
23 article, "In a review of 24,000 patients  
24 who were medically prescribed opioids,

1     only seven could be found who got into  
2     trouble with them. So a chronic pain  
3     patient becoming addicted to opioid  
4     medications is definitely the exception  
5     rather than the rule."

6                     Do you see that?

7             A.     Yes.

8             Q.     Do you know what is -- what  
9     the citations for the 24,000 patients who  
10    were medically prescribed opioids with  
11    only seven who could be found who got  
12    into trouble with them?

13            A.     I don't. And this looks  
14    like a draft for the reasons that we're  
15    still trying to determine what the  
16    appropriate journal would be. So there  
17    may be more information that we have --  
18    than we have here.

19            Q.     Does that ring any bells  
20    with you? That's a fairly large study,  
21    24 thousand patients, with respect to  
22    addiction to prescribed opioids. Does  
23    that ring any bells?

24            A.     The study that might have

1     been cited by this doesn't jump out at me  
2     at the moment.

3             Q.     If the study -- if this  
4     article was published, that would be  
5     cited, correct?

6             A.     If the final draft was  
7     published, this may or may not be in, we  
8     would need to look and see under a  
9     different type -- under further review,  
10    whether this was appropriate or not or  
11    whether it was there or not.

12            Q.     Sure. But if it was there,  
13    it would be typical that there would be a  
14    citation for something like that, where  
15    there's actually data presented, correct?

16            A.     For -- when this type of a  
17    statement is made, it's typically  
18    referenced.

19                   MS. CONROY: That's all I  
20    have. Thank you.

21                   THE VIDEOGRAPHER: Off the  
22    record switch? Or do you want to  
23    stay there?

24                   MR. LIFLAND: I can do it

1           here. I've only got about three  
2           or four very quick questions.

3                       - - -

4                       EXAMINATION

5                       - - -

6       BY MR. LIFLAND:

7           Q.       Let's go back and pull out  
8       Exhibit 23. This is the e-mail that  
9       attaches the Imagine the Possibilities  
10      Pain Coalition.

11           A.       Yes.

12           Q.       And my question is, did  
13      Janssen continue with this initiative  
14      after the meetings that are described in  
15      these --

16           A.       No, they did not. The  
17      e-mail documentation here indicates that  
18      we -- that this -- this pivotal program  
19      was terminated.

20           Q.       And you're referring to the  
21      Bates stamp number JAN-MS-02057429?

22           A.       Yes, that's correct.

23           Q.       And what does it say there?

24           A.       At the bottom it says, "A

1 decision to discontinue the Imagine The  
2 Possibilities Pain Coalition was rendered  
3 in December 2012 resulting from a lack of  
4 available resources to continue funding  
5 the initiative."

6 Q. Just a few quick questions  
7 about the promotional review committee on  
8 which you sat. Were you representing  
9 marketing on the promotional review  
10 committee?

11 A. No, I was not.

12 Q. Were you representing sales  
13 on the promotional review committee?

14 A. No, I was not.

15 Q. Were you representing  
16 compliance on the promotional review  
17 committee?

18 A. No, I was not.

19 Q. And in fact, there was  
20 another compliance officer who sat on the  
21 committee?

22 A. That is correct.

23 Q. You were representing  
24 medical affairs?

1           A.     Correct.

2           Q.     And what was your role as  
3     the representative of medical affairs?

4           A.     My role as the  
5     representative for medical affairs on the  
6     promotional review committee was to  
7     ensure medical -- help to ensure medical  
8     accuracy of the information that was  
9     being developed.

10                   MR. LIFLAND: No further  
11                   questions.

12                               -   -   -

13                               EXAMINATION

14                               -   -   -

15     BY MS. CONROY:

16           Q.     Doctor, do you recall in  
17     January of 2014, I'll show it -- it  
18     appears -- or I may be able to find  
19     copies of it. January 16, 2014. You  
20     probably have it there, I think.

21                   An e-mail. You were asked  
22     some questions by Martha Popsner and Amit  
23     Patel about promotional speaker bureau  
24     training. Do you recall being involved

1 in promotional speaker bureau training  
2 sessions?

3 A. Yes.

4 Q. And they had asked you about  
5 upcoming speaker training for Nucynta and  
6 they had questions concerning the  
7 presentation of some materials.

8 And I'll put -- I'll wait to  
9 put something. I have some writing on  
10 this document, so I'll wait until we have  
11 a clean copy.

12 I don't know if you can see  
13 it. But the question is -- of course you  
14 can't see it.

15 I'll read you the e-mail.

16 "Hi Gary. I'm wondering if you would  
17 mind reviewing a slide Amit and I  
18 developed for the upcoming speaker  
19 training this weekend on comparative  
20 claims for Nucynta and Nucynta ER. You  
21 are so familiar with this audience, more  
22 than Amit and I, and we value your  
23 opinion on the presentation of this  
24 information."



1                   And then you respond: "The  
2       statements contained within the  
3       directive" -- I'm sorry.

4                   "The statements contained  
5       within reflect the direction that the  
6       company has been given our speakers."

7                   So let me have a copy of  
8       this now. Let me pass this to you as  
9       Exhibit 26.

10                   (Document marked for  
11       identification as Exhibit  
12       Janssen-Vorsanger-26.)

13       BY MS. CONROY:

14               Q.     And what I'm going to ask  
15       you about is the attachment. It's  
16       JAN-MS-00606393 with a native file 6394.

17                   And my question with respect  
18       to this final page where you apparently  
19       review the -- the comparative efficacy  
20       and safety claims concerning Nucynta ER  
21       and Oxycodone CR, you were -- you were in  
22       a position to advise your colleagues with  
23       respect to what types of comparative  
24       statements could be made at a speakers

1 bureau training facility, correct?

2 A. I'd like -- I'd like to read  
3 the document.

4 Q. Yeah. Go right ahead.

5 A. I'm sorry, I'm -- I'm not  
6 sure what your question is at this point.

7 Q. You were -- you were well  
8 versed enough in this subject to be able  
9 to respond to Ms. Popsner and Mr. -- or  
10 maybe it's Ms. or Mrs. or Mr. Patel, with  
11 respect to questions they had about what  
12 could be said at a promotional speakers  
13 bureau training conference.

14 A. They asked me questions  
15 about the type of information that could  
16 be included as part of healthcare  
17 compliance guidance for the meeting. And  
18 the information that was discussed was  
19 that what we have down here, is it  
20 permissible to make efficacy and safety  
21 comparisons between Nucynta and Oxycodone  
22 IR or Nucynta ER or Oxycodone ER, and the  
23 direction was the Oxycodone CR was used  
24 for assay sensitivity and these were not

1 active comparators in the clinical  
2 studies and they were not designed for  
3 head to head, therefore, it's not  
4 appropriate to make comparisons between  
5 the efficacy and safety as part of these  
6 activities.

7 Q. Correct. And even though  
8 you were not primarily responsible for  
9 marketing or for sales or for compliance,  
10 you were able to provide the company  
11 direction to individuals that were  
12 working on training the speakers bureau?

13 A. This is based on the  
14 clinical trial design and the medical  
15 aspects of it, which was my -- what was  
16 my function in medical affairs.

17 Q. Right.

18 A. So they would have had to  
19 opine on the approach from a compliance  
20 perspective. Because, one, these were  
21 regulatory and compliance officers. I  
22 couldn't give them that. I can just say  
23 that the way this was described was  
24 consistent with the company's approach on

1     how to describe the clinical data.

2             Q.     Well, let's take a look at  
3     your response to them. It's not about  
4     the clinical trial. It says, "The  
5     statements contained within reflect the  
6     direction that the company has been given  
7     our speakers."

8             A.     Right. So clinically these  
9     were not head-to-head studies. They  
10    weren't statistically powered and  
11    prespecified to look at differences in  
12    efficacy and tolerability between the  
13    doses of tapentadol selected. Despite  
14    this, we have opted to just discuss the  
15    primary efficacy endpoint and make  
16    statements relating to tapentadol and  
17    placebo and that Oxycodone was used for  
18    assay sensitivity.

19                So as someone with  
20    experience in clinical trial, explaining  
21    to them on study design on how it would  
22    be done, this would be appropriate to  
23    inform them. The decisions on what they  
24    would communicate through healthcare

1 compliance guidelines would have been the  
2 responsibilities of the compliance  
3 officer.

4 Q. I understand that would be  
5 the final arbiter of the compliance, but  
6 you were -- you were well versed and  
7 understood what it would be appropriate  
8 to say or not say to a speaker, correct?

9 A. Based on the data and the --  
10 and the extent of what the data could or  
11 could not be used.

12 Q. Right. You would understand  
13 what could be said to a speaker with --  
14 you would understand what could or could  
15 not be used when speaking to key opinion  
16 leaders or speakers?

17 A. About clinical studies. Not  
18 about necessarily what would be  
19 appropriate from a compliance or  
20 regulatory perspective.

21 Q. Correct. My point is, that  
22 you did understand what could be used  
23 from clinical studies with respect to  
24 promotional materials or speaking to key

1 opinion leaders or speakers that were on  
2 a bureau?

3 A. I'm still not -- I'm not  
4 exactly understanding the point that  
5 you're trying to make. As someone in  
6 medical affairs which was knowledgeable  
7 about the studies, speaking with  
8 individuals who may not have that degree  
9 of trial expertise was explaining how the  
10 data would be analyzed and how the data  
11 would be used. It's not -- I'm not  
12 totally --

13 Q. So you did not have an  
14 understanding of what would or would not  
15 be appropriate to be said either to sales  
16 representatives, to healthcare  
17 professionals or to key opinion leaders,  
18 you would only be able to tell compliance  
19 what the results of the clinical trial  
20 were?

21 A. That would be the primary  
22 focus. They would need to see -- they  
23 would need to understand what was  
24 permissible or not permissible by the

1 rules for FDA. But I would certainly be  
2 in a position, as I did -- I believe I  
3 did here, is to explain the results of  
4 the clinical study.

5 Q. What did you mean when you  
6 said, "The statements contained within  
7 reflect the direction that the company  
8 has been given our speakers"?

9 A. Right. So the first part of  
10 it would say, is it permissible to make  
11 efficacy and safety comparisons between  
12 Nucynta and Oxycodone IR and Nucynta and  
13 Oxycodone CR and the company's position  
14 was, as it's stated here, that Oxycodone  
15 was included for assay sensitivity and  
16 these were not active comparators in the  
17 clinical study, which is correct. And  
18 the studies were not designed to make  
19 head-to-head comparisons which is also  
20 correct. Therefore it's not appropriate  
21 to make comparisons between the efficacy  
22 and safety of Nucynta and Oxycodone IR or  
23 Nucynta ER and Oxycodone ER. So these  
24 were statements that if people were out

1     talking about our products, we wanted to  
2     make sure that they weren't overstating  
3     the efficacy that we had which was  
4     appropriate. Those would have been  
5     direction, as you know, from FDA, to make  
6     sure that the data are fair balanced and  
7     completely reflect what we actually did.

8                     And there are examples here  
9     that talk about what you could not say.  
10    So these are examples of inappropriate  
11    comparisons based on some of the clinical  
12    trials.

13                    Q.     Did you or did you not  
14    understand what was appropriate to be  
15    said out to healthcare professionals or  
16    to individuals on a speakers bureau about  
17    the results of clinical trials?

18                    A.     Yes. The clinical trial  
19    data, I understand what you could explain  
20    what the studies did or did not say, and  
21    that could communicate in peer -- in  
22    conversation with these peer-to-peer  
23    individuals.

24                    Q.     I didn't hear the very end



1 of your answer.

2 A. Yeah, so yes, the results of  
3 clinical trials I did understand, and  
4 would communicate the results of those  
5 studies in a conversation with our  
6 speakers.

7 Q. And you understand the  
8 rules -- you understood the rules, you  
9 understood what you could say and what  
10 you could not say?

11 A. Based on FDA direction on  
12 what we were allowed to say on levels of  
13 efficacy.

14 Q. So it was more than just an  
15 understanding of the clinical trial  
16 results. You also, as someone in medical  
17 affairs, had an understanding of what --  
18 what was appropriate and not appropriate  
19 to say about clinical trials?

20 A. I could certainly weigh in,  
21 but I was not the ultimate arbiter. That  
22 would have been through regulatory  
23 affairs.

24 Q. Correct. Ms. Popsner did

1 not contact regulatory affairs?

2 A. She is regulatory affairs.

3 Q. So regulatory affairs came  
4 to you?

5 A. Regulatory affairs came to  
6 me to ensure that there was -- that what  
7 they were saying was clinically correct.

8 Q. Do you recall any other  
9 times that they came to you for  
10 assistance?

11 A. They came to me for  
12 assistance as part of members of the  
13 promotional review committee where they  
14 wanted to have a better understanding of  
15 what the data actually meant and  
16 potentially what the clinical  
17 implications of those data would be. So  
18 my role as a medical reviewer and  
19 somebody from medical affairs was to  
20 provide that type of expertise to explain  
21 what some of the clinical trial data  
22 mean.

23 Q. Would this have been  
24 something that arose out of the

1 promotional review committee or would  
2 this have been outside that?

3 A. This would have been  
4 something that would have been reviewed  
5 by the promotional review committee as  
6 part of the materials that would have  
7 been shared as part of speaker training.

8 Q. So the -- whatever this  
9 slide is or whether it was part of a  
10 slide deck, the promotional review  
11 committee would review this slide deck?

12 A. Yes.

13 Q. And I'm not suggesting, you  
14 don't know the years that you were on it,  
15 so you don't know if you would have  
16 reviewed this anyway, correct?

17 A. Yes. Moreover -- yes, I  
18 don't know exactly when this was done.  
19 And it's associated with an e-mail, but  
20 this is something that I probably --  
21 likely would have seen.

22 MS. CONROY: Okay. I have  
23 no further questions. Thanks.

24 MR. LIFLAND: I think we're

1 done.

2 THE VIDEOGRAPHER: Okay.

3 The time is 4:36 p.m., December 6,

4 2018. Going off the record,

5 completing the videotaped

6 deposition.

7 (Excused.)

8 (Deposition concluded at

9 approximately 4:36 p.m.)

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CERTIFICATE

I HEREBY CERTIFY that the  
witness was duly sworn by me and that the  
deposition is a true record of the  
testimony given by the witness.

It was requested before  
completion of the deposition that the  
witness, GARY VORSANGER, Ph.D., M.D.,  
have the opportunity to read and sign the  
deposition transcript.

---

MICHELLE L. GRAY,  
A Registered Professional  
Reporter, Certified Shorthand  
Reporter, Certified Realtime  
Reporter and Notary Public  
Dated: December 11, 2018

(The foregoing certification  
of this transcript does not apply to any  
reproduction of the same by any means,  
unless under the direct control and/or  
supervision of the certifying reporter.)

1 INSTRUCTIONS TO WITNESS

2

3 Please read your deposition  
4 over carefully and make any necessary  
5 corrections. You should state the reason  
6 in the appropriate space on the errata  
7 sheet for any corrections that are made.

8 After doing so, please sign  
9 the errata sheet and date it.

10 You are signing same subject  
11 to the changes you have noted on the  
12 errata sheet, which will be attached to  
13 your deposition.

14 It is imperative that you  
15 return the original errata sheet to the  
16 deposing attorney within thirty (30) days  
17 of receipt of the deposition transcript  
18 by you. If you fail to do so, the  
19 deposition transcript may be deemed to be  
20 accurate and may be used in court.

21

22

23

24

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Page 722

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ACKNOWLEDGMENT OF DEPONENT

3

4

I, \_\_\_\_\_, do

5

hereby certify that I have read the

6

foregoing pages, 420 - 724, and that the

7

same is a correct transcription of the

8

answers given by me to the questions

9

therein propounded, except for the

10

corrections or changes in form or

11

substance, if any, noted in the attached

12

Errata Sheet.

13

14

15

16

\_\_\_\_\_  
GARY VORSANGER, Ph.D., M.D.                      DATE

17

18

19

Subscribed and sworn

to before me this

20

\_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.

21

My commission expires: \_\_\_\_\_

22

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\_\_\_\_\_  
Notary Public

24



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Page 724

1	LAWYER'S NOTES		
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16	_____	_____	_____
17	_____	_____	_____
18	_____	_____	_____
19	_____	_____	_____
20	_____	_____	_____
21	_____	_____	_____
22	_____	_____	_____
23	_____	_____	_____
24	_____	_____	_____